

SOUTH CAROLINA HEALTH PLANNING COMMITTEE

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South Carolina Health Planning Committee
 Department of Health & Environmental Control
 Certificate of Need Program
 2600 Bull Street
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CHAPTER I

INTRODUCTION

SOUTH CAROLINA HEALTH PLAN

The South Carolina Code of Laws requires the Department of Health and Environmental Control ("Department") to prepare a South Carolina Health Plan ("Plan"), with the advice of the Health Planning Committee, for use in the administration of the Certificate of Need Program. See [§ 44-7-180\(B\)](#).

CERTIFICATE OF NEED

The purpose of the Certificate of Need Program, as set forth in the *State Certification of Need and Health Facility Licensure Act* ("Certificate of Need Act"), is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State. To achieve these purposes, the Certificate of Need Act requires a [person](#) or [health care facility](#) to obtain a Certificate of Need from the Department before undertaking certain health care related projects. See [§§ 44-7-120 and 44-7-160](#).

HEALTH PLANNING COMMITTEE

The Health Planning Committee advises the Department in the drafting of the South Carolina Health Plan. It is comprised of fourteen members, twelve of whom are appointed by the Governor, which must include at least one member from each congressional district. One member is appointed by the chairman of the Department's Board, and by virtue of his office, the final member is either the South Carolina Consumer Advocate or his designee. Health care consumers, health care financiers (including business and insurance), and health care providers (which must include at least one [administrator of a non-profit nursing home administrator](#)) are equally represented. The Health Planning Committee reviews the South Carolina Health Plan and submits it to the Board of Health and Environmental Control for final revision and adoption. See [§ 44-7-180\(A\)\(C\)](#).

STATUTORY REQUIREMENTS

In accordance with [§ 44-7-180\(B\)](#), this Plan contains (1) an *inventory* of existing health care facilities, beds, [specified health](#) services and equipment; (2) *projections of need* for additional [healthcare](#) facilities, beds, [specified health](#) services, and equipment; (3) *standards for distribution* of [healthcare](#) facilities, beds, [specified health](#) services, and equipment ("Certificate of Need Standards"); and (4) the *project review criteria considered to be the most important in evaluating taken into consideration of Certificate of Need applications for each*

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type of facilities, beds, services and equipment.

(1) INVENTORY

Chapter II of this Plan identifies the inventory regions and service areas used in the administration of the Certificate of Need Program. Healthcare facilities, specified health services, beds and equipment are inventoried where applicable.

(2) PROJECTIONS OF NEED

Chapters III – XII of this Plan discuss the need for additional healthcare facilities, beds, specified health services and equipment in the State. While the methodologies used to determine these needs vary depending on the type of healthcare facility, bed, specified health service, or equipment, a determination of both current and projected need is calculated for most areas addressed by the Plan. Charts summarizing these needs are located in Chapter XIII of this Plan.

(3) CERTIFICATE OF NEED STANDARDS

In consultation with the Health Planning Committee, the Department formulated these standards to guide medical health providers throughout the State. Inclusion of these standards in the application process is designed to give applicants notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished projects.

(4) PROJECT REVIEW CRITERIA

A general statement has been added to most sections of the Plan setting forth the Project Review Criteria considered to be the most important in reviewing Certificate of Need applications for each type of healthcare facility, bed, specified health service, and equipment. These criteria are not listed in order of importance, but sequentially, as they are in Regulation 61-15. Where appropriate, the Plan contains a finding as to whether the benefits of improved accessibility to each such type of facility, service and equipment may outweigh the adverse effects caused by the duplication of any existing facility, service or equipment.

DISCLAIMERS

- (1) The hyperlinks provided throughout this Plan were checked for accuracy immediately prior to publication. Due to factors outside our control, we cannot guarantee the links will not expire or otherwise become unavailable after publication. Should you be unable to access the hyperlinked information, please feel free to request the information from the Certificate of Need Program via e-mail to coninfo@dhec.sc.gov.

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- (2) The population data set forth in this Plan was received from the South Carolina Revenue and Fiscal Affairs Office in ~~February~~ **March** of 2015~~5~~⁷. The material includes population projections that are subject to the following conditions:

These projections offer only one scenario of future population change using the most current data available. The overall accuracy of the projections depends on the extent to which future events unfold in a manner that reflects previous trends observed within each group. The model cannot account for unprecedented events that may significantly alter an area's demographic composition in the future. The possible events include large factory openings or closings, changes in technology, public health crises, environmental events, or other conditions that could have an effect on migration, birth rates, or death rates. This means that population projections are likely to be more accurate in the immediate future than in distant years into the future. The projections will be updated regularly as new data becomes available and future events unfold. Annual county population estimates released by the Census Bureau will be monitored along with births~~s~~ and deaths~~s~~ data released each year, and adjustments will be made to the projected population results as appropriate.

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CHAPTER II

INVENTORY REGIONS AND SERVICE AREAS

INVENTORY REGIONS

This Plan has adopted the [Department's regions](#) for the purpose of inventorying [Health Care Facilities](#) and [Health Services](#) as designated and enumerated below:

<u>Region</u>	<u>Counties</u>	
I - Upstate	Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, and Union	Formatted: Font: (Default) Open Sans, 11 pt
II - Midlands	Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda and York	Formatted: Font: (Default) Open Sans, 11 pt
III - Pee Dee	Chesterfield, Clarendon, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter and Williamsburg	Formatted: Font: (Default) Open Sans, 11 pt
IV - Lowcountry	Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper and Orangeburg	Formatted: Font: (Default) Open Sans, 11 pt
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NEED FOR HEALTH CARE FACILITIES AND HEALTH SERVICES

This Plan calculates the need for certain Health Care Facilities and Health Services throughout South Carolina based on certain formula and criteria set forth in detail in this Plan. For example:

- The need for hospital beds is based on the utilization of individual facilities.
- The need for acute psychiatric services, alcohol and drug abuse services, comprehensive rehabilitation services, and residential treatment centers for children and adolescents is based on various service areas and utilization methodologies specified in this Plan.
- The need for most health services (e.g., cardiac catheterization, open heart surgery) is based upon the service standard, which is a combination of utilization criteria and ~~travel time distance~~ requirements.
- The need for long-term care and skilled nursing ~~home~~ services is projected by county.
- ~~Institutions serving a restricted population throughout the state are planned on a statewide basis.~~

SERVICE AREAS

In addition to inventory regions, this Plan designates service areas for certain Health Care Facilities and Health Services. ~~A-These service areas may be is~~ comprised of one or more counties, ~~and may cross multiple administrative, geographic, trade and/or political boundaries. Due to factors that may include availability, accessibility, personal or physician preferences, insurance and managed care contracts or coverage, or other reimbursement issues, patients may seek and receive treatment outside the county or inventory region in which they reside and/or outside of the State. Therefore, service Service~~ areas may specifically cross inventory regions. The need for a service is analyzed by ~~an~~ assessment of existing resources and need in the relevant service area, along with other factors set forth in this Plan, applicable statutes and regulations.

EXCEPTIONS TO SERVICE AREA STANDARDS TRANSFER BETWEEN AFFILIATED FACILITIES

~~The health care delivery system is in a state of evolution both nationally and in South Carolina. Due to the health reform movement, a number of health care facilities are consolidating and establishing provider networks in order to better compete for contracts within the new environment. This is particularly important for the smaller, more rural facilities that run the risk of being bypassed by insurers and health care purchasers looking for the availability of comprehensive health care services for their subscribers.~~

Given the ever-changing nature of the health care delivery system, affiliated hospitals facilities may sometimes want to transfer or exchange specific technologies or licensed beds in order to better meet an identified need. Affiliated hospitals, Affiliated facilities are two or more health care facilities, whether inpatient or outpatient, owned, leased, sponsored, or who have a formal legal relationship with a central organization and whose relationship has been established for reasons other than for transferring beds, equipment or services. In certain instances such a transfer or exchange of acute services could be accomplished in a cost-effective manner and result in a more efficient allocation of health care resources. This transfer or exchange of services applies to both inpatient and outpatient services; ~~however, such transfers or exchanges could only occur between facilities within the same licensing category.~~ *A Certificate of Need is required to transfer or exchange health services.* In order to evaluate a proposal for the transfer or exchange of any health care technology reviewed under the Certificate of Need program, the following criteria must be applied to it:

1. A transfer or exchange of beds and/or services may be approved only if there is no overall increase in the number or amount of such beds and/or services.
2. ~~Although such transfers may cross county or service area lines, the facilities must be located within the one-way driving time established for the proposed service of each other, as determined by the Department. A transfer or exchange initiated under this Chapter may only occur within the service area(s) established in this Plan.~~

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3. The facility receiving the beds and/or services must demonstrate the need for the additional capacity based on both historical and or projected utilization patterns.
4. The applicants must explain the impact of transferring the technology on the health care delivery system of the county and/or service area from which it is to be taken; any negative impact must be detailed, along with the perceived benefits of the proposal.
5. The facility giving up the beds and/or services may not use the loss of such beds and/or services as justification for a subsequent request to establish or re-establish such beds and/or services.
6. A written contract or agreement between the governing bodies of the affected affiliated facilities approving the transfer or exchange of beds and/or services must be included in the Certificate of Need process.
7. Each facility giving up a beds and/or services must acknowledge in writing that this exchange is permanent; any further transfers would be subject to this same process.

ESTIMATED STATE CIVILIAN POPULATION

Where these projections were required for calculations, this Plan has been developed using the estimated civilian population of 4,774,839 for 2013 and projected population of 5,116,870 for 2020. All population data (county, planning area, and statewide) were provided by the South Carolina Revenue and Fiscal Affairs Office, Health and Demographics Section, in February of 2015.

INVENTORY DATES

Only those facilities reviewed under the Certificate of Need program are included in the inventory. The cut-off date for inclusion of information in this Plan was September 12, 2014. Inventory and utilization data set forth in this Plan is derived from the 2013-2015 Joint Annual Reports (JARs). The period of time in which the individual data was collected is set forth by the reporting entity in its individual JAR submission.

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CHAPTER III

ACUTE CARE HOSPITALS

GENERAL HOSPITALS

Relevant Definitions

"Hospital" means a facility organized and administered to provide overnight medical, surgical, or nursing care of illness, injury, or infirmity and may provide obstetrical care, and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

Hospital may include residential treatment facilities for children and adolescents in need of mental health treatment which are physically a part of a licensed psychiatric hospital. This definition does not include facilities which are licensed by the Department of Social Services.

"Hospital Bed" means a bed for an adult or child patient. Bassinets for the newborn in a maternity unit nursery, beds in labor rooms, recovery rooms, and other beds used exclusively for emergency purposes are not included in this definition.

Bed Capacity

For existing beds, capacity is considered bed space designated exclusively for inpatient care, including space originally designed or remodeled for inpatient beds, even though temporarily not used for such purposes. The number of beds counted in any patient room is the maximum number for which adequate square footage is provided, except that single beds in single rooms have been counted even if the room contained inadequate square footage.

Inventory and Bed Need

All licensed general hospitals, including Federal facilities, are listed in the inventory. Patient days and admissions are as reported by the hospital in its JAR. The number of patient days utilized for the general hospital bed need calculations does not include days of care rendered in licensed psychiatric units, substance abuse units, or comprehensive rehabilitation units of hospitals. These days of care are shown in the corresponding inventories for each type of service. In addition, the days of care provided in Long-Term Care hospitals are not included in the general bed need calculations.

Total capacity by survey refers to a total designed capacity or maximum number of beds that may be accommodated as determined by an on-site survey. This capacity may exceed the

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number of beds actually set up and in use. It may also differ from the licensed capacity, which is based on State laws and regulations. Beds have been classified as conforming and nonconforming, according to standards of plant evaluation.

Variable Occupancy Rate

The General Acute Hospital bed need methodology uses the following variable occupancy rate factors:

0 - 174 bed hospitals → 65%
175 - 349 bed hospitals → 70%
350+ bed hospital → 75%

The population and associated utilization are broken down by age groups. The use rates and projected average daily census are made for the age cohorts of 0-17, 18-64, and 65 and over, in recognition that different population groups have different hospital utilization rates. ~~For some hospitals, different age groups were used based on the data provided by the facility.~~

Where the term “hospital bed need” is used, these figures are based upon utilization data for the general acute hospitals. This term does not suggest that facilities cannot operate at higher occupancy rates than used in the calculations without adding additional beds.

Availability

~~Many rural hospitals in South Carolina are struggling financially. Chesterfield General Hospital and Marlboro Park Hospital ceased operation in April of 2015. With the closings of these hospitals, residents of several South Carolina counties (Bamberg, Barnwell, Chesterfield, Lee, Marlboro, McCormick and Saluda) counties no longer have a local hospital in their counties.~~ Calhoun County is served by the Regional Medical Center of Orangeburg and Calhoun Counties. The need for general hospital beds is determined through the consideration of current utilization and projected population growth with the goal of having beds available within approximately thirty (30) ~~minutes~~ minutes’ travel time for the majority of the residents of the State.

CERTIFICATE OF NEED PROJECTION AND STANDARDS

1. Calculations of hospital bed need are made for individual hospitals, ~~because of the differing occupancy factors used for individual facilities, then and summed totaled by county or service area to get determine~~ the overall ~~county~~ service area bed need.
2. ~~For individual hospitals, the methodology for calculating hospital bed need is as follows:~~

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- a. Determine the current facility use rate by dividing the current utilization by the current population in each of the three age cohorts.
 - b. Multiply the current facility use rate by age cohort by the projected population for seven years in the future by age cohort (in thousands) and divide by 365 to obtain a projected average daily census by age cohort.
 - c. Divide the sum of the age cohort projected facility average daily census by the variable occupancy (.65/.70/.75) to determine the number of beds needed to meet the hospital's need.
 - d. The number of additional beds needed or excess beds for the hospital is obtained by subtracting the number of existing beds from the bed need.
 - e. The totals for each hospital in a county or service area are summed to determine whether there is an overall projected surplus or need for additional beds.
3. If a ~~county or~~ service area indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the ~~county~~/service area indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical unit at either the existing hospital site or another site, if the existing hospital is relocating or has relocated in whole or in part to that site. The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.
4. If there is a need for additional hospital beds in the ~~county or~~ service area, then any entity may apply to add these beds within the ~~service area~~~~county~~, and any entity may be awarded the Certificate of Need for these beds. If the number of beds needed is less than 50, then up to a total of 50 beds could be approved for any entity at any location within the ~~county~~/service area. An applicant requesting additional beds beyond those indicated as needed by the methodology stated above, must document the need for additional beds based on historical and projected utilization, ~~floor plan layouts,~~ projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.

5. A facility may apply to create a new additional hospital at a different site within the same ~~county or~~ service area through the transfer of existing licensed beds, the projected bed need for the facility, or a combination of both existing beds and projected bed needs. The facility is not required to have a projected need for additional beds in order to create a new additional hospital. There is no required minimum number of beds in order to approve the CON application. The applicant must justify, through patient origin and other data, the need for a new hospital at the chosen site and the potential adverse impact a new hospital at the chosen site could have on the existing hospitals in the ~~county or~~ service area.
6. No additional hospitals will be approved unless ~~they are~~ it is a general hospital and will provide:
- A 24-hour emergency services department, ~~and meet that~~ meets the requirements to be a Level III emergency service as defined in the *Emergency Services* section of Regulation 61-16;
 - Inpatient medical services to both surgical and non-surgical patients; ~~and~~
 - Medical and surgical services on a daily basis within at least six of the major diagnostic categories as recognized by Centers for Medicare and Medicaid Services (CMS). Any applicant for a new hospital must provide a written commitment that the facility will accept Medicare and Medicaid patients and that unreimbursed services for indigent and charity patients are provided at a percentage ~~which that~~ meets or exceeds other hospitals in the ~~county or~~ service area. The CMS Diagnostic Categories Chart is located in Chapter XIII of this Plan.
7. Due to the low utilization and the low capital cost of converting hospital-based nursing home, psychiatric, rehabilitation and/or substance abuse beds to general acute care hospital beds, the following policies may apply:
- Hospitals that have licensed nursing home beds within the hospital may be allowed to convert ~~these~~ nursing home beds to general acute care hospital beds only within the hospital, provided the hospital can document an actual need for ~~these~~ additional general acute care beds. Need will be based on actual utilization, using current information. *A Certificate of Need is required for this conversion.*
 - Existing ~~general acute care~~ hospitals that have inpatient psychiatric, rehabilitation, or substance abuse beds may be allowed to convert ~~such these specialty~~ beds to acute care hospital beds, regardless of the projected need for general acute care hospital beds, ~~provided a~~ *Certificate of Need is received*

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required for this conversion.

8. In some areas of South Carolina, a considerable influx of tourists is not counted in the permanent population. If an individual hospital in these areas can document and demonstrate the need for additional beds due to non-resident (tourist) population and seasonal utilization fluctuations due to this population, then, based on further analysis, the Department may approve some additional beds at the existing hospital.
9. ~~Should the deletion of services at a federal facility result in an immediate impact on the utilization of a hospital, then the Department may approve a request for additional beds at the affected hospital. Should a hospital request additional beds due to the deletion of services at a Federal facility that results in the immediate impact on the utilization of the hospital, then additional beds may be approved at the affected hospital.~~ The impacted ~~affected~~ hospital must document ~~this the~~ increase in demand and explain why additional beds are needed to accommodate ~~the care of~~ patients previously served at ~~a the f~~ederal facility. ~~Based on the analysis of utilization provided by the affected hospital, the Department may approve some additional hospital beds to accommodate this immediate need.~~
10. Changes in the delivery system due to health care reform have resulted in the consolidation of facilities and the establishment of provider networks. These consolidations and agreements may lead to situations where affiliated hospitals may wish to transfer beds between themselves in order to serve their patients in a more efficient manner. *A proposal to transfer or exchange hospital beds requires a Certificate of Need* and must comply with the ~~following criteria~~ provisions outlined in Chapter II, Exceptions to Service Area Standards Transfer between Affiliated Facilities:
 - a. ~~A transfer or exchange of beds may be approved only if there is no overall increase in the number of beds;~~
 - b. ~~Such transfers may cross county lines; however, the applicants must document with patient origin data the historical utilization of the receiving facility by residents of the county giving up beds;~~
 - c. ~~Should the response to criterion b fail to demonstrate a history of residents of the county transferring the beds utilizing the receiving facility, the applicant must document why it is in the best interest of those residents to transfer the beds to a facility with no historical affinity for them;~~
 - d. ~~The applicant must explain the impact of transferring the beds on the health care delivery system of the county from which the beds are to be taken; any negative impact must be detailed, along with the perceived benefits of such an agreement;~~

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- ~~e. The facility receiving the beds must demonstrate the need for the additional capacity based on both historical and projected utilization patterns;~~
- ~~f. The facility giving up the beds may not use the loss of these beds as justification for a subsequent request for the approval of additional beds;~~
- ~~g. A written contract or agreement between the governing bodies of the affected facilities approving the transfer or exchange of beds must be included in the Certificate of Need application;~~
- ~~h. Each facility giving up beds must acknowledge in writing that this exchange is permanent; any further transfers would be subject to this same process.~~

11. Factors to be considered regarding modernization of facilities include:

- a. Functional arrangement of the facility as it relates to efficient handling of patients and related workloads.
- b. The ability to update medical technology within the existing plant.
- c. Existence of The Joint Commission (TJC) or other accreditation body deficiencies or "grandfathered" licensure deficiencies.
- d. Cost efficiency of the existing physical plant versus plant revision, etc.
- e. Private rooms are now considered the industry standard.

12. Each modernization proposal must be evaluated on the basis of merit, cost efficiency, and impact on health ~~care~~ delivery ~~and status~~ within the service area.

The Hospital Bed Need Chart is located in Chapter XIII of this Plan, at the end of this Chapter.

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- 1. Compliance with the Need Outlined in this Section of this Plan;
- 2. Community Need Documentation;
- 3. Distribution (Accessibility);
- 4. Acceptability;
- 5. ~~Financial Feasibility~~ Record of the Applicant;

6. Cost Containment; and
7. Adverse Effects on Other Facilities.

General hospital beds are ~~typically~~ located within approximately thirty (30) ~~minutes~~~~minutes'~~ travel time for the majority of the residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.

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LONG-TERM ACUTE CARE HOSPITALS

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Long-Term Acute Care Hospitals (LTACHs) are hospitals with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients. They provide treatment to patients with complex medical conditions, such as strokes, cardiac care, ventilator dependency, wound care and post-surgical care.

A LTACHs may be either a freestanding facility, or may occupy space in another hospital ("hospital-within-a-hospital"). Hospitals must meet additional ~~f~~ederal criteria in order to qualify as a LTACH ~~Hospital~~ under the "hospital-within-a-hospital" model:

1. The new ~~hospital~~LTACH must have a governing body, which is distinct and separate from the governing body of the host hospital, and the new body cannot be under the control of the host hospital or any third entity that controls both hospitals.
2. The LTACH must have a separate Chief Executive Officer through whom all administrative authority flows, who is not employed by, or under contract with, the host hospital or any third entity that controls both hospitals.
3. The ~~hospital~~LTACH must have a separate Chief Medical Officer who reports directly to the governing body and is responsible for all medical staff activities. The Chief Medical Officer cannot be under contract with the host hospital or any third entity that controls both hospitals.
4. The ~~hospital~~LTACH must have a separate medical staff ~~from the medical staff of the host hospital,~~ which reports directly to the governing body, ~~and adopt bylaws~~ governing medical care, including granting privileges to individual practitioners.

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

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1. An application for a ~~Long-Term Acute Care Hospital~~LTACH must be in compliance with the relevant standards in [Regulation 61-16](#) (*Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*).
2. Although ~~LTACH~~~~Acute-Care Hospital~~ beds are not considered to be a separate

category for licensing purposes, they will be inventoried separately from general acute care hospital beds for planning purposes.

3. The utilization of LTACHs is not included in the bed need for general acute care hospital beds. No bed need will be calculated for ~~Long-Term Acute Care Hospital~~LTACH beds. An applicant must document the need for LTACH beds based on the utilization of existing LTACH beds.
4. A hospital that has leased general beds to a ~~Long-Term Acute Care Hospital~~LTACH shall be entitled to regain these beds once the lease is terminated. No entity other than the hospital ~~(or its successor)~~ that initially leased the general acute beds ~~(or its successor)~~ to the ~~Long-Term Acute Care Hospital~~LTACH shall be entitled to ~~obtain the rights to~~ the beds upon termination of the lease. *A Certificate of Need application is required:*
 - a. A hospital may be allowed to convert these former LTACH beds to general acute hospital beds regardless of the projected need for general acute beds;
 - b. A hospital may be allowed to convert these former LTACH beds to psychiatric, inpatient treatment facility, rehabilitation, or other specialty beds only if there is a bed need projected for this proposed other category of licensed beds.
5. A hospital which ~~seeks~~desires to be designated as ~~a~~an LTACH, and has been awarded a CON for that purpose, must be certified as ~~a~~an LTACH by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. The entity that has had its CON revoked shall not have the authority to operate as a general acute care hospital.
5. ~~A hospital that desires to be designated as a Pediatric LTACH must restrict admissions to patients under the age of 21 who require long-term medical care. Should the facility attempt to provide care that is inconsistent with this requirement or patient demand or other economic conditions require the facility to close, the Certificate of Need issued to that hospital for that purpose shall be revoked.~~

The Long-Term Acute Care Hospitals Chart is located in Chapter XIII of this Plan at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Compliance with the Need Outlined in this Section of this Plan;

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2. Community Need Documentation;
3. Distribution (Accessibility);
4. ~~Financial Feasibility~~ Record of the Applicant.

Long-Term Acute Care Hospital beds are located within approximately sixty (60) minutes ~~minutes'~~ travel time for the majority of the residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.

CRITICAL ACCESS HOSPITALS (CAH)

~~Rural counties often encounter higher unemployment rates, a greater preponderance of low-paying jobs that do not provide health insurance, and a larger elderly population than found in more urban counties. Rural hospitals are usually smaller than urban hospitals, with fewer physicians and other health care professionals, and diagnostic and therapeutic technology is generally less available. They typically have a high Medicare and Medicaid case mix, but receive lower reimbursement from Medicare than urban facilities. At the same time, many rural hospitals are the sole community provider and one of the major employers in the community. The loss of a rural hospital has a major impact on the delivery of health services for the citizens of a community.~~

The South Carolina Department of Health and Human Services administers programs through the Medicaid program to assist struggling rural hospitals. One such program designates rural hospitals as Critical Access Hospitals (CAH) who are then eligible for more favorable Medicaid reimbursement methodology. ~~Another program seeks to award funds up to \$4 million to struggling rural hospitals (designated as "Advising Hospital") from a \$40 million allocation in South Carolina Budget Proviso 33.33 for FY 2014/2015 known as the "Hospital Transformation Pool" although to date no such funds have been disbursed. Provisions in President Obama's FY 2016 Budget call for additional cuts to the funding of rural hospitals including either cuts in cost-based reimbursements to CAHs or the elimination of that designation.~~

~~The Department is in the process of considering changes to the requirements for hospitals operating in rural counties to allow for the development of a cost-effective facility with a free-standing emergency room, surgical facilities and a small number of acute care hospital beds.~~

A CAH is intended to provide essential health services to rural communities. Converting a struggling rural hospital to a CAH can allow a community to maintain local health access that would otherwise be lost. CAHs are subject to review by the [Independent Payment Advisory Board \(IPAB\)](#), whereas other hospitals are not currently subject to IPAB review.

~~The following criteria must be met in order for a facility to qualify as a CAH:~~

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1. ~~It must be located in a rural county. It may be either an existing facility or a hospital that closed or downsized to a health center or clinic after November 29, 1989. A facility may be allowed to relocate or rebuild provided it meets the CMS criteria.~~
2. ~~The facility must be part of a rural health network with at least one full-service hospital, with agreements regarding patient referral and transfer, communications, and patient transportation.~~
3. ~~The facility must be located more than 35 miles from any other hospital or CAH (15 miles for areas with only secondary roads) or must have been certified by the State prior to January 1, 2006 as being a necessary provider of health care services to residents of the area.~~
4. ~~The maximum number of licensed beds is 25, which can be operated as any combination of acute or swing beds.~~
5. ~~Required services include inpatient care, emergency care, laboratory and pharmacy.~~
6. ~~Emergency services must be available 24 hours a day, with on-call personnel available within 30 minutes. CMS requires that any hospital, including a CAH, that does not have a physician on site 24 hours per day, 7 days per week, provide a notice to all patients upon admission that addresses how emergency services are provided when a physician is not on site.~~
7. ~~The medical staff must consist of at least one physician. Staffing must include nursing on a 24-hour basis; other staffing can be flexible. Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists can provide inpatient care without their supervising physician(s) being on site.~~
8. ~~The annual average length of stay must be less than 96 hours (4 days).~~

In South Carolina, a hospital located in an urban Metropolitan Statistical Area (MSA) county can still be considered "rural" for the purposes of the CAH program if it meets the following criteria:

1. ~~It is enrolled as both a Medicaid and Medicare provider and accepts assignment for all Medicaid and Medicare patients.~~
2. ~~It provides emergency health care services to indigent patients.~~
3. ~~It maintains a 24-hour emergency room.~~
4. ~~It staffs 50 or fewer acute care beds.~~

5. ~~It is located in a county with 25% or more rural residents, as defined by the most recent Census.~~

The impact of the Critical Access Hospital Program in South Carolina is a financial one, allowing cost-based reimbursement from Medicare for a facility choosing to participate. The designation as a CAH does not require a change in the licensing of an existing hospital. However, a hospital may be required to de-license a number of beds in order to meet the 25-bed requirement.

The designation of a hospital as a Critical Access Hospital *does not require Certificate of Need review* because it does not change the licensing category of the facility. However, an [exemption](#) from Certificate of Need review is required for a hospital to reduce its number of licensed beds in order to meet the criteria for a CAH. *Should a hospital later desire to revert to a general acute hospital, a Certificate of Need is required*, but the facility may be permitted to increase the number of licensed hospital beds up to the prior number of beds *without regard or affect to the current bed need shown in the service area.*

The [Critical Access Hospitals Chart](#) is located ~~in Chapter XIII of this Plan~~ *at the end of this Chapter.*

PERINATAL REGIONS

The Perinatal Regions referred to in the Obstetrical Services and Neonatal Services sections below are distinct from the Department's Regions defined in Chapter II of this Plan, and are identified by the name of its designated Regional Perinatal Center.

<u>Perinatal Region</u>	<u>Counties</u>
<u>I - Greenville Memorial</u>	Abbeville, Anderson, Edgefield, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Saluda
<u>II - Spartanburg Regional</u>	Cherokee, Chester, Spartanburg, Union
<u>III - Palmetto Health Richland</u>	Aiken, Allendale, Bamberg, Barnwell, Calhoun, Clarendon, Fairfield, Kershaw, Lancaster, Lee, Lexington, Newberry, Orangeburg, Richland, Sumter, York
<u>IV - McLeod Regional</u>	Chesterfield, Darlington, Dillon, Florence, Horry, Marion, Marlboro, Williamsburg
<u>V - MUSC Medical</u>	Beaufort, Berkeley, Charleston, Colleton, Dorchester, Hampton, Jasper, Georgetown

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PERINATAL SERVICE LEVELS

Because the cost of high-risk obstetrical and neonatal services is so great, it is not desirable or cost-effective for all hospitals in the State to provide the higher levels of care. Over the years, a regionalized approach to perinatal care has been implemented in South Carolina to address the need for high quality, risk-appropriate, cost-effective perinatal health care. Regionalization provides a coordinated system of perinatal care for a well-defined population group. Each hospital providing perinatal services is designated by the Department's Division of Health Licensing as a Level I, II, III, or IV Perinatal Hospital, or a Regional Perinatal Center (RPC). Each Level I, II, III and IV hospital maintains a relationship with its designated RPC for consultation, transport and continuing education. Patients are transferred to the appropriate RPC when medically appropriate, if beds are available. In this way, quality care is provided to mothers and newborn infants, and specially trained perinatal personnel and intensive care facilities can be used efficiently and cost-effectively.

The complete descriptions of the five levels of perinatal services described briefly below are outlined in the Section of [Regulation 61-16](#), entitled *Designation of Inpatient Perinatal Care Services*.

[Basic Perinatal Center with Well Newborn Nursery \(Level I\)](#). Level I hospitals provide services for normal uncomplicated pregnancies. A full list of the requirements for a Level I Basic Perinatal Center with Well Newborn Nursery can be found at Regulation 61-16, Section 1306.A. *Certificate of Need review is not required to establish a Level I program.*

[Specialty Perinatal Center with Special Care Nursery \(Level II\)](#). In addition to the requirements of Regulation 61-16, Section 1306.A, Level II hospitals provide services for both normal and selected high-risk obstetrical and neonatal patients. A full list of the requirements for a Level II Specialty Perinatal Center can be found at Regulation 61-16, Section 1306.B. *Certificate of Need review is not required to establish a Level II program.*

[Subspecialty Perinatal Center with Neonatal Intensive Care Unit \(Level III\)](#). In addition to the requirements of Regulation 61-16, Sections 1306.A and 1306.B, Level III hospitals provide all aspects of perinatal care, including intensive care and a range of continuously available, subspecialty consultation as recommended in the most recent edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. A full list of the requirements for a Level III Subspecialty Perinatal Center with Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.C. *Certificate of Need Review is required to establish a Level III program.*

[Regional Perinatal Center with Neonatal Intensive Care Unit \(RPC\)](#). In addition to the requirements of Regulation 61-16, Sections 1306.A through 1306.C, RPCs provide consultative, outreach, and support services to other hospitals in the region. A full list of the

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requirements for a Regional Perinatal Center can be found at Regulation 61-16, Section 1306.D. No more than one Regional Perinatal Center will be approved in each perinatal region. *Certificate of Need Review is required to establish a RPC.*

Complex Neonatal Intensive Care Unit (Level IV). In addition to the requirements of Regulation 61-16, Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. A full list of the requirements for a Complex Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.E. A Level IV hospital need not act as a Regional Perinatal Center (RPC). *Certificate of Need Review is required to establish a Level IV program.*

The Perinatal-Capable Facilities Chart is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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OBSTETRICAL SERVICES

Advances in obstetrical and newborn intensive care offer the promise of lower perinatal mortality and improvement in the quality of life for survivors. The high cost of intensive care and the limited availability of skilled personnel have created the requirement for a more efficient method of resource allocation.

Maternal, fetal, and neonatal mortality and morbidity rates can be significantly reduced if patients at high risk are identified early in the pregnancy and optimum techniques for the care of both the mother and infant are applied. High-risk deliveries are a small percent of total annual deliveries, but these patients require a high degree of specialized care. In 2013, 80.481.7% of all Very Low Birthweight (VLB) babies were born in either a Level III center or a Regional Perinatal Center, whereas the Healthy People 2020 national objective was 82.5%.

Infant mortality is defined as the death of babies from birth until their first birthday. South Carolina's infant mortality rate for 2015 was 6.97.0 infant deaths per 1,000 live births versus the national rate of 5.826.0 infant deaths per 1,000 births in 2014.

Neonatal mortality is the death rate for infants up to 28 days old. For 2015, South Carolina's neonatal mortality rate for all races was 4.6 neonatal deaths per 1,000 live births, while the Healthy People 2020 national objective was 4.1 neonatal deaths per 1,000 live births.

The need for obstetrical beds will be evaluated based on information supplied by the Joint Annual Report of Hospitals and other sources. Those facilities experiencing low utilization and in close proximity to one another should consider consolidating services, where appropriate.

The [OB Utilization and Births Chart](#) and [Intermediate Bassinet Need Chart](#) are located in ~~Chapter XIII of this Plan, at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered the most important in evaluating Certificate of Need applications for an obstetrical service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Distribution (Accessibility);
3. Acceptability;
4. ~~Financial Feasibility~~ [Record of the Applicant](#); and
5. Adverse Effects on Other Facilities.

The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

NEONATAL SERVICES

Neonatal services are highly specialized and are only required by a very small percentage of infants. The need for these services is affected by the incidence of high-risk deliveries, the percentage of live births requiring neonatal services, and the average length of stay. The limited need for these services requires that they be planned for on a regional basis, fostering the location of these specialized units in hospitals that have the necessary staff, equipment, and consultative services and facilities. Referral networks facilitate the transfer of infants requiring this level of services from other facilities.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The projected need for neonatal intensive care bassinets is calculated on a regional basis:
 - a. For each region take the average number of births from 201~~34~~-201~~53~~ and the average population of women age 15-44 for 201~~34~~-201~~53~~ to generate an average birth rate.
 - b. Multiply the average birth rate against the projected 201~~97~~ population of women age 15-44 to project the number of births in 201~~97~~.

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- c. ~~Calculate the average number of patient days per region by combining and then dividing the patient days for 2012 and 2013. Generate the projected number of intensive care bassinets in a region by applying a constant of 4.0 bassinets per 1,000 live births to the projected birth rate.~~
- d. ~~Divide the projected 2017 births by the actual 2013 births to compute a growth rate in the number of births. Any Level III, Level IV, or RPC neonatal unit may request additional intensive care bassinets beyond those indicated as needed by the methodology above. The Level III, Level IV, or RPC neonatal unit requesting the addition must document the need for additional intensive care bassinets based on historical and projected utilization, projected population growth, routine swing of intermediate care bassinets into the intensive care setting, or other factors demonstrating the need for the proposed bassinets.~~
- e. ~~The average number of patient days for 2012-2013 is multiplied against the growth rate to project the number of patient days for 2017.~~
- f. ~~The projected number of patient days for 2017 is divided by a 65% occupancy factor to generate the projected number of NICU bassinets in a region.~~

- 2. Only Level III, Level IV, and RPCs neonatal units have intensive care bassinets.

The [Intensive and Intermediate Bassinets Chart](#), [Utilization of Neonatal Special Care Units Chart](#) and [NICU Bed Need Chart](#) are located ~~in Chapter XIII of this Plan at the end of this Chapter.~~

The addition of neonatal intermediate care bassinets does not require Certificate of Need review. The need for intermediate neonatal bassinets is calculated based on the utilization of the individual providers using a 65% occupancy factor. Note that some Level II hospitals did not report any utilization for the intermediate care bassinets and the occupancy rate is reflected as zero, which decreases the need calculations.

~~South Carolina presently has 2.9 neonatal intensive care bassinets and 12 neonatal intermediate care bassinets per 1,000 births.~~

~~In some areas the number of intensive care bassinets should be increased. The intermediate care bassinets should be better utilized in Level II facilities so babies can be transferred back closer to their home community, potentially alleviating the high utilization of the current intensive/intermediate care bassinets in RPC facilities in some areas of the State. To improve the availability of the existing RPC neonatal intensive care bassinets, utilization of the back transport concept should be supported. This component of regionalized care involves the transfer of infants who no longer require neonatal intensive care to facilities with intermediate or continuing care bassinets appropriate to the individual baby's care needs.~~

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~~If more back transfers to the Level II facilities occurred, then some of the overcrowding problems of the existing RPC units would be alleviated.~~

It should be noted that some RPC, Level III, and Level IV facilities with intensive care bassinets may at times have intermediate type infants in intensive care bassinets and vice versa as the patient load changes within the unit. RPCs may use intermediate and intensive care bassinets interchangeably as the level of care required by the neonate varies.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following criteria are considered the most important in evaluating Certificate of Need applications for a neonatal service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Distribution (Accessibility);
3. Acceptability
4. ~~Financial Feasibility~~Record of the Applicant; and
5. Adverse Effects on Other Facilities.

Because neonatal services are planned and located regionally due to the small percentage of infants requiring neonatal services, this service is available within approximately 90 ~~minutes~~minutes' travel time for the majority of the population. ~~Of more importance is the early identification of mothers who potentially will give birth to a baby needing this specialized service and directing them to the appropriate neonatal center. There is a need for additional intensive care bassinets in some areas. A few additional Level II (intermediate) bassinets are needed; however, the existing intermediate care bassinets are not used in some hospitals.~~ The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

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PEDIATRIC INPATIENT SERVICES

~~A pediatric inpatient unit is a specific section, ward, wing or unit devoted primarily to the care of medical and surgical patients less than 18 years old, not including special care for infants. It is recognized that children have special problems that need to be addressed by specialized facilities, equipment and personnel experienced in dealing with children, and understanding and sympathetic to the child's unique needs. It is also recognized that each hospital need not develop the capability to provide all types of pediatric care. Pediatric beds are licensed as general hospital beds and no separate need is calculated for them.~~

CERTIFICATE OF NEED STANDARDS

1. ~~There may be a need for additional pediatric beds in the existing general hospitals; however, additional beds for pediatric services will not be approved unless other beds~~

~~are converted to pediatrics or a need is indicated in the Plan for additional hospital beds.~~

- ~~2. The benefits of improved accessibility do not outweigh the adverse effects caused by the duplication of this existing service.~~

~~In many hospitals, pediatric beds/services are not physically separated from other general hospital beds. Only larger hospitals have distinct pediatric units. General hospital beds are located within approximately 30 minutes travel time for the majority of the residents of the State.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following criteria are considered the most important in evaluating Certificate of Need applications for this service:~~

- ~~1. Compliance with the Need Outlined in this Section of this Plan;~~
- ~~2. Distribution (Accessibility);~~
- ~~3. Acceptability;~~
- ~~4. Financial Feasibility; and~~
- ~~5. Adverse Effects on Other Facilities.~~

PEDIATRIC LONG-TERM ACUTE CARE HOSPITALS

~~Pediatric Long-Term Acute Care Hospitals (PLTACHs) are specialized health care facilities that provide care for children up to age 21 who have complex medical conditions that require extensive care on a long-term basis (similar to adult LTACHs). Care may be rehabilitative or palliative. These facilities are designed to be as non-institutional as possible while meeting the psychological, physical, and emotional needs of chronically ill children and their families. To be admitted, children must have ongoing health conditions that require both medical and nursing supervision and specialized equipment or services.~~

~~Patients often have three or more chronic conditions. Many are non-ambulatory and dependent on medical technology such as ventilators, feeding tubes, IV infusions, and mobility devices.~~

~~Despite the need for Pediatric LTACH services, the State has no such facility at this time. Candidates are currently either staying for extended periods in one of the State's Children's Hospitals or are receiving daily therapy in their own homes. The establishment of a Pediatric LTACH would provide an important treatment option for these children.~~

~~Pediatric LTACH facilities are currently located primarily in the Northeast and California. They are potentially a less costly alternative to maintaining these children in an acute care~~

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facility. ~~Some states have nursing homes that specialize in extended care for pediatric patients, but there are currently no such facilities in South Carolina.~~

CERTIFICATE OF NEED STANDARDS

1. ~~An application for a Pediatric Long-Term Acute Care Hospital must be in compliance with the relevant standards in the Department's Regulation 61-16.~~
2. ~~Although Pediatric Long-Term Acute Care Hospital beds are not considered to be a separate category for licensing purposes, they will be inventoried separately from general acute care hospital beds for planning purposes.~~
3. ~~The utilization of PLTACHs is not included in the bed need for general acute care hospital beds. No bed need will be calculated for Pediatric Long-Term Acute Care Hospital beds. An applicant must document the need for PLTACH beds.~~
4. ~~An applicant for PLTACH beds must submit an affiliation agreement with one of the State's children's hospitals. This affiliation agreement will at a minimum include a transfer agreement and coverage for specialized medical services.~~
5. ~~Should a hospital lease general beds to another entity to create a Pediatric Long-Term Acute Care Hospital, that hospital shall be entitled to regain these beds once the lease is terminated. No entity other than the hospital that initially leased the general acute beds (or its successor) to the Pediatric Long-Term Acute Care Hospital shall be entitled to obtain the rights to the beds upon termination of the lease. *A Certificate of Need application is required.*~~
6. ~~A hospital that desires to be designated as a Pediatric LTACH must restrict admissions to patients under the age of 21 who require long-term medical care. Once licensed, a Pediatric LTACH must remain licensed as such. Should the facility attempt to provide care that is inconsistent with this requirement or patient demand or other economic conditions require the facility to close, the Certificate of Need issued to that hospital for that purpose shall be revoked. The entity that has had its Certificate of Need revoked shall not have the authority to operate as a general acute care hospital and the licensed beds operated by the facility will be removed from the bed inventory.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:~~

1. ~~Compliance with the Need Outlined in this Section of this Plan;~~
2. ~~Community Need Documentation;~~

3. ~~Distribution (Accessibility);~~
4. ~~Financial Feasibility.~~

~~There are currently no Pediatric Long-Term Acute Care Hospital beds in South Carolina. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.~~

CHAPTER IV

PSYCHIATRIC SERVICES

COMMUNITY PSYCHIATRIC BEDS

Inpatient psychiatric services are those services provided to patients who are admitted to institutions for the evaluation, diagnosis and treatment of mental, emotional or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.

Special units for children, adolescents and geriatric patients have been developed throughout the State. If any additional beds are approved, they must come from the calculated psychiatric bed need in this Plan. These specialty psychiatric services should be identifiable units with sufficient space to have available areas for sleeping, dining, education, recreation, occupational therapy and offices of evaluation and therapy. The unit should be staffed with an appropriate multi-disciplinary care team of psychiatrists, psychologists, social workers, nurses, occupation therapists, recreational therapists, and psychiatric technicians. Other consultants should be available as needed.

~~According to the Department of Mental Health (DMH), there continues to be a great need for additional psychiatric beds and resources in communities throughout the state. Medicaid does not pay for psychiatric care provided by freestanding psychiatric hospitals (known as Institutions for Mental Disease or IMDs); however, the Emergency Medical Treatment & Labor Act (EMTALA) requires hospitals to provide psychiatric care for patients regardless of ability to pay. As a result, general hospitals have found their emergency departments overburdened with patients requiring psychiatric care. DMH has had substantial decreases over the past 15 years in the number of its available adult inpatient psychiatric beds, and for many years has lacked the capacity to timely admit adult patients referred for emergency admission. Additionally, many general hospitals have reduced or eliminated their adult psychiatric hospital beds.~~

~~CMS's ongoing project called the Medicaid Emergency Psychiatric Demonstration could lead to Medicaid reimbursement for freestanding psychiatric hospitals. Twelve participating states, including North Carolina, will create Medicaid programs for psychiatric patients age 21-64 seeking emergency treatment at IMDs. The theory is that the IMDs can provide care at lower cost than warehousing the patients in hospital EDs. If the pilot project is successful, Congress may revise the Medicaid funding for psychiatric care nationally. Project results may be released as early as July of 2015.~~

The [Psychiatric Programs Chart](#) is located in Chapter XIII of this Plan at the end of this Chapter.

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Need projections are based on psychiatric service areas. The service areas are consistent for psychiatric services, inpatient alcohol and drug abuse facilities, and inpatient residential treatment facilities for children and adolescents.

2. The bed need methodology takes the greater of the actual utilization of the facilities in the service area or 87.5% of the statewide average beds per 1,000 population to project need. For service areas without existing psychiatric units and related utilization data, the statewide average beds per 1,000 population was used in the projections.

2. Should the service area show a need for additional beds, a general acute care hospital may be approved for the maximum of the actual projected bed need or up to 20 additional beds ("20 Bed Rule") to establish an economical unit ("Unit"). An applicant seeking more beds than are projected may not use such beds for the establishment of a specialty psychiatric unit. Any beds sought in excess of the projected bed need in the service area must be used for the provision of general adult psychiatric services in order to address the growing number of psychiatric patients being held in hospital emergency departments. Finally, although more than one general acute care hospital per service area may apply for beds under this provision, the Department may approve no more than nineteen (19) beds, in any combination, beyond the need shown in this Plan for each service area.

In the absence of a projected need for beds in a psychiatric service area, an existing facility can apply to add up to 5 additional beds, given that it has achieved an occupancy rate of at least 70% as reported on the most recent Joint Annual Report ("JAR").

An existing general acute care hospital or freestanding psychiatric facility that already has licensed psychiatric beds may apply for additional beds beyond the need demonstrated in the Plan. However, prior to applying for additional beds beyond the need demonstrated in the Plan, the facility must demonstrate that it has maintained a minimum 70% occupancy rate as demonstrated by its most recent Joint Annual Report ("JAR"). The Department shall not approve an application for more beds than are shown as needed in the Plan unless the applicant meets this 70% occupancy rate criteria.

3. Priority should be given to excess general hospital beds that can be economically and cost effectively converted for use as a specialized psychiatric unit over the construction of new beds, if such beds will be accessible to the target population.

The Psychiatric Bed Need Chart is located in Chapter XIII of this Plan at the end of this

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Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. ~~Compliance with the Need Outlined in this Section of this Plan;~~
2. Community Need Documentation;
3. Distribution (Accessibility);
4. Acceptability;
5. ~~Financial Feasibility~~Record of the Applicant;
6. Ability of the Applicant to Complete the Project;
7. Cost Containment; and
8. Staff Resources.

Psychiatric beds are planned for and located within sixty ~~minutes~~minutes' travel time for the majority of the residents of the State. In addition, current utilization and population growth are factored into the methodology for determining psychiatric bed need. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these services.

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STATE MENTAL HEALTH FACILITIES

Psychiatric Hospital Beds

DMH operates a variety of psychiatric facilities. DMH has analyzed the patient population and plans to provide psychiatric services in the least restrictive environment, maintain patients in the community and keep hospitalization to a minimum. Since DMH cannot refuse any patient assigned to them by a court, renovation, replacement and expansion of the component programs should be allowed as long as the overall psychiatric hospital complement is maintained or reduced. As long as DMH does not add any additional beds over the 3,720 beds that were in existence on July 1, 1988, any changes in facility bed capacity *would not require Certificate of Need review.*

Local Inpatient Crisis Stabilization Beds

DMH reports there are an insufficient number of adult inpatient psychiatric beds in a number of regions of the State. As a result of this situation, significant numbers of persons in a behavioral crisis are being held in hospital emergency rooms for inordinate periods of time until an appropriate inpatient psychiatric bed becomes available. These emergency room patients may not have a source of funding.

DMH has attempted to alleviate this problem by means of its "Crisis Stabilization Program." Within available funding limits, the "Crisis Stabilization Program" is to provide short-term emergency stabilization of psychiatric patients in the local community, by use of both local hospital beds and non-hospital residential programs, such as community residential care facilities, for those patients who do not require a hospital level of care. For patients needing stabilization in a hospital, subject to available funding, DMH contracts with one or more local hospitals willing to admit indigent patients assessed by DMH as needing acute care in return for a daily rate for a defined period. These patients can be cared for in licensed general acute care beds or licensed psychiatric beds.

To assist in alleviating this problem, the following policies will apply:

- a. *A Certificate of Need is not required* to convert existing acute care beds or existing psychiatric beds to create Crisis Stabilization services pursuant to a contract with DMH.
- b. *A Certificate of Need is required* to add psychiatric beds pursuant to a contract with DMH to provide Crisis Stabilization services. These additional beds could be approved if the Plan indicates a need for additional beds or some small number (ten beds or less) of additional beds could be approved for crisis stabilization patients only. These beds would not be restricted to any specific age group except that the patients would have to be over age 18.
- c. An application for a Certificate of Need for Crisis Stabilization patients only must be accompanied by information from DMH to verify this additional need, such as the number of patients currently awaiting treatment, the estimated average length of stay, the pay source for the patients, the number of patients emergently admitted to DMH hospitals over the past year from the area, the number of crisis patients that are expected to require this service annually, and other information to justify these additional psychiatric beds. In addition, DMH will supply verification that it made contact with all hospitals in the county and contiguous counties to notify them of the potential for adding some psychiatric beds to the area. The hospital seeking the Certificate of Need will provide the necessary care for these individuals referred by DMH and may be reimbursed for the care of the patients if there are sufficient funds, but the hospital must identify the minimum number of indigent (no source of funding) patient days it will provide to patients referred by DMH. Should the contract with DMH terminate for any reason or should the hospital fail to provide care to the patients referred from DMH, the license for these beds will be voided.

If justified by DMH, the Department will consider converting inpatient psychiatric beds to other levels of care provided that alternative community-based resources are not available. Patients appropriate for de-institutionalization should be discharged when the appropriate

community support services are in place.

William J. McCord Adolescent Treatment Facility (MOVE TO FOOTNOTE)

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The William J. McCord Adolescent Facility provides substance abuse treatment for adolescents statewide. It received a Certificate of Need on 7/16/10 to convert to a specialized hospital with 15 psychiatric beds restricted primarily for the provision of alcohol and drug abuse treatments for adolescents. The bed classification change was made in order to continue receiving reimbursement. These beds are not counted in the psychiatric bed need calculations.

DEPARTMENT OF MENTAL HEALTH INITIATIVES

The South Carolina General Assembly approved a pilot project in 2011 to assess the provision of psychiatric crisis stabilization services for patients age 65 and over in Critical Access Hospitals (CAHs). Participating facilities could establish a ten-bed Distinct Part Psychiatric unit for Prospective Payment System Exclusion, as defined by the Federal Centers for Medicare and Medicaid Services (CMS) for the purpose of conducting this project. If a participating hospital de-licensed beds prior to the commencement of the project in order to qualify as a CAH, the facility may re-license up to 10 of the original bed complement in order to participate, pursuant to a written exemption from the Department. A Certificate of Need was not required for participation in the project.

DMH requested and received assistance from The Duke Endowment to develop a telepsychiatry network for all South Carolina hospitals operating emergency departments. Modern, high-speed interactive video conference equipment will be purchased by DMH through public procurement, including a three-year warranty for such equipment and placed in local participating hospitals containing emergency departments and directly linked to DMH where psychiatrists will be available for psychiatric consultation. Springs Memorial Hospital of Lancaster is participating in the program as part of its establishment of a Geriatric Psychiatric Unit pursuant to SC-12-29.

CHAPTER V

REHABILITATION FACILITIES

A Rehabilitation Facility is operated for the primary purpose of providing comprehensive physical rehabilitation services through an intensive, coordinated team approach for patients with severe physical ailments. These facilities should be located where an extensive variety of professionals representing medical, psychological, social, and vocational rehabilitation evaluation and services are available. These beds are viewed as being comprehensive in nature and not limited only to a particular service or specialty. CMS identifies 13 specific conditions for which facilities must treat 60% of their patients ("the compliance threshold") in order to qualify for Medicare reimbursement. Certain comorbidities as specified in 42 CFR 412.29(b)(1) must be used to determine the compliance threshold.

Most general hospitals and other health care facilities offer physical rehabilitation services such as physical therapy, occupational therapy, speech therapy, or occupational therapy without the involvement of a formal interdisciplinary program. In addition, some hospitals have consolidated their rehabilitation services into a single unit to improve the coordination of care for acute patients in their facilities. These consolidations are intended to improve the quality of care for patients currently being treated in the facility and are not considered to be providing comprehensive physical rehabilitation services as defined in this section of the Plan.

The [Rehabilitation Programs Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

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1. The need for beds is calculated based on rehabilitation service areas.
2. The methodology takes the greater of the actual utilization of the facilities in the service area or the statewide average number of beds per 1,000 of the 65+ population cohort to project need.
3. For service areas without existing rehabilitation units and related utilization data, 75% of the overall state use rate was used in the projections.

The [Rehabilitation Bed Need Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

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The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- ~~1. Compliance with the Need Outlined in this Section of this Plan;~~
- ~~2.1. Community Need Documentation;~~
- ~~3.2. Distribution (Accessibility);~~
- ~~4.3. Projected Revenues;~~
- ~~5.4. Projected Expenses; and~~
- ~~6.5. Cost Containment; and~~
- ~~7. Resource Availability.~~

Rehabilitation facilities are now located throughout the state and are available within approximately sixty (60) ~~minutes~~^{minutes} travel time for the majority of residents. Such facilities should be located where an extensive variety of health care professionals are available. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

Statewide Programs

The South Carolina Vocational Rehabilitation Center operates a 30-bed facility in West Columbia to serve the vocational training needs of the disabled.

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CHAPTER VI

ALCOHOL AND DRUG ABUSE FACILITIES

There are six types of licensed substance abuse treatment facilities in South Carolina. These are (1) outpatient facilities, (2) social detoxification centers, (3) freestanding medical detoxification facilities, (4) residential treatment programs, (5) inpatient treatment services, and (6) narcotic treatment programs.

OUTPATIENT FACILITIES

An outpatient facility provides treatment, care and services to individuals dependent upon or addicted to psychoactive substances and their families based on an individual treatment plan in a nonresidential setting. The length and intensity of outpatient treatment varies according to the severity of the individual's illness and response to treatment. There are currently 71 licensed "Outpatient Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence" in South Carolina, with a total of 98 locations.

CERTIFICATE OF NEED STANDARDS

A Certificate of Need is not required for outpatient facilities as described above.

SOCIAL DETOXIFICATION FACILITIES

A social detoxification facility provides supervised withdrawal from alcohol or other drugs in which neither the client's level of intoxication nor physical condition is severe enough to warrant direct medical supervision or the use of medications to assist in withdrawal, but which maintains medical backup and provides a structured program of counseling, if appropriate, educational services, and referral for further rehabilitation. It provides 24-hour-a-day observation of the client until discharge.

CERTIFICATE OF NEED STANDARDS

A Certificate of Need is not required for a social detoxification facility.

FREESTANDING MEDICAL DETOXIFICATION FACILITIES

A freestanding medical detoxification facility is a short-term residential facility, separate from an inpatient treatment facility, providing for medically supervised withdrawal from psychoactive substance-induced ~~intoxification~~intoxication, with the capacity to provide screening for medical complications of alcoholism and/or drug abuse, a structured program of counseling, if appropriate, and referral for further rehabilitation. Detoxification facilities

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are envisioned as being physically distinct from inpatient treatment facilities, although there are no prohibitions against an inpatient facility providing detoxification services to its clients as needed. There are currently 4 freestanding medical detoxification facilities located in the State, operated by local County Alcohol and Drug Abuse Agencies.

The [Freestanding Medical Detoxification Facilities Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Medical detoxification services are allocated by Department region service area.
2. Facilities can be licensed for a maximum of sixteen (16) beds in order to meet federal requirements.
3. Because a minimum of ten (10) beds is needed for a medical detoxification program, a ten (10) bed unit may be approved in any service area without an existing detoxification unit, provided the applicant can document the need.
4. Additional facilities are needed for the services to be accessible within sixty (60) ~~minutes~~ minutes travel time for the majority of state residents.
5. ~~The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- ~~1. Compliance with the Need Outlined in this Section of the Plan;~~
- ~~2.1.~~ 1. Distribution (Accessibility);
- ~~3.2.~~ 2. Projected Revenues;
- ~~4.3.~~ 3. Projected Expenses;
- ~~5.4.~~ 4. Ability of the Applicant to Complete the Project;
- ~~6.5.~~ 5. Cost Containment; and
- ~~7.6.~~ 6. Staff Resources.

Additional facilities are needed for the services to be accessible within sixty (60) minutes travel time for the majority of state residents. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

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RESIDENTIAL TREATMENT PROGRAM FACILITIES

A residential treatment program facility is a 24-hour facility offering an organized service in a residential setting, which is designed to improve the client's ability to structure and organize the tasks of daily living and recovery through planned clinical activities, counseling, and clinical monitoring in order to promote successful involvement or re-involvement in regular, productive, daily activity, and, as indicated, successful reintegration into family living. Residential treatment programs utilize a multi-disciplinary staff for clients whose biomedical and emotional/behavioral problems are severe enough to require residential services and who are in need of a stable and supportive environment to aid in their recovery and transition back into the community. Twenty-four hour observation, monitoring, and treatment shall be available.

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

A Certificate of Need is not required for a Residential Treatment Program.

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INPATIENT TREATMENT FACILITIES

An inpatient treatment facility is a short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital. ~~Inpatient treatment facilities must comply with either Regulation 61-93 or Regulation 61-16. For reference purposes only, these facilities are also subject to compliance with Regulation 61-16.~~

The [Inpatient Treatment Facilities Chart](#) is located ~~in Chapter XIII of this Plan at the end of this Chapter.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Need projections are calculated by service area. Because patients in need of alcohol and/or drug abuse treatment frequently require psychiatric treatment services as well, the inpatient treatment service areas mirror the psychiatric service areas (e.g., Anderson/Oconee, Greenville/Pickens, etc.) to facilitate planning in a manner that recognizes the comorbidity of this patient population.
2. The bed need methodology takes the greater of the actual utilization of the facilities in the service area or the statewide beds per 1,000 population to project need.
3. For service areas without existing ~~inpatient treatment facilities~~ ~~psychiatric units~~ and

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related utilization data, the state use rate was used in the projections.

4. Because a minimum of 20 beds is needed for an inpatient program, a 20-bed unit may be approved in a service area that does not have any existing beds provided the applicant can document the need.

5. ~~In the absence of numerical a projected need in the service area, an existing inpatient treatment facility can apply to add up to 5 additional inpatient treatment beds if it has achieved an occupancy rate of at least 70% as reported on its most recent Joint Annual Report ("JAR").~~

4.

5-6. Inpatient treatment facilities are physically distinct from freestanding detoxification centers. Applicants may not combine the bed need for freestanding detoxification with the bed need for inpatient treatment in order to generate a higher bed need for an inpatient facility. There are no prohibitions against an inpatient facility providing detoxification services to its clients as needed, but the bed need projections refer to two distinct treatment modes that cannot be commingled.

6-7. The establishment of a regional treatment center ~~that to serves~~ more than a single service area may be proposed in order to improve access to care for patients in service areas that ~~do not currently have such services available~~ are not currently well served. Such a proposed center would be allowed to combine the bed need for ~~a separate, contiguous service areas, provided that each service area to be combined shows a positive bed need without existing services with another service area providing this other service area shows a need for additional beds.~~ The applicant must document with patient origin data the historical utilization of the residents in the service area that is to be combined, or why it is in the best interest of these residents for their projected bed need to be used to form a regional treatment facility.

7-8. It is frequently impossible for a facility to totally predict or control short-term deviation in the number of patients with mixed psychiatric/addictive etiology ~~to their illnesses~~. Therefore, in the case of facilities with licensed beds for both psychiatric and substance abuse treatment, the Department will allow deviations of up to 25% of the total number of licensed beds as swing beds to accommodate patients having diagnoses of both psychiatric and substance abuse disorders.

8. ~~Services are accessible within sixty (60) minutes travel time for the majority of residents of the state.~~

9. Current utilization and population growth are factored into the methodology for determining the need for additional beds.

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~~10. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

~~1. Compliance with the Need Outlined in this Section of the Plan;~~

1. Distribution (Accessibility);
2. Projected Revenues;
3. Projected Expenses;
4. Ability of the Applicant to Complete the Project;
5. Cost Containment; and
6. Staff Resources.

Services are accessible within sixty (60) ~~minutes~~ minutes' travel time for the majority of residents of the state. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

The [Inpatient Treatment Bed Need Chart](#) is located ~~in Chapter XIII of this Plan~~at the end of this Chapter.

NARCOTIC TREATMENT PROGRAMS

Narcotic treatment programs provide medications for the rehabilitation of persons dependent on opium, morphine, heroin or any derivative or synthetic drug ~~of that group~~. Opioid maintenance therapy (OMT) is an umbrella term that encompasses a variety of pharmacologic and non-pharmacologic treatment modalities, including the therapeutic use of specialized opioid compounds such as methadone, suboxone and buprenorphine to psychopharmacologically occupy opiate receptors in the brain, extinguish drug craving and thus establish a maintenance state. OMT is a separate service that can be provided in any level of care, as determined by the client's needs. ~~For reference purposes only, N~~narcotic treatment programs are described in [Regulation 61-93](#).

Charges for medication usually range between \$11 and \$17 per day. A Registered Pharmacist must dispense the medication. ~~A minimum caseload of around 150 clients is required to ensure breaking even on the costs of providing this service.~~

The [Narcotic Treatment Programs Chart](#) is located ~~in Chapter XIII of this Plan~~at the end of this Chapter.

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

~~1. A Certificate of Need is required for a narcotic treatment program.~~

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~~1. An applicant must project a minimum caseload of 150 clients. Because clients must usually attend a center 6 days per week to receive their dose of medication, these centers should be located throughout the state, with at least one center per county. To improve accessibility, narcotic treatment programs should be developed in counties where none exist.~~

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~~2. An additional treatment program can only be approved in a county with an existing program if the applicant is able to document sufficient need for the service.~~

~~2.~~

~~3. According to the licensing standards~~For reference purposes only, Regulation 61-93 states that a narcotic treatment program shall not operate within 500 feet of: the property line of a church, the property line of a public or private elementary or secondary school, a boundary of any residential district, a public park adjacent to any residential district, or the property line of a lot devoted to residential use.

~~4. Because clients must usually attend a center 6 days per week to receive their dose of medication, these centers should be located throughout the state. To improve accessibility, narcotic treatment programs should be developed in counties where none exist. An additional treatment program can only be approved in a county with an existing program if the applicant is able to document that the existing program has a sufficient waiting list for admission that would justify the need for an additional program.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- ~~1. Compliance with this Plan~~Community Need Documentation;
2. Distribution (Accessibility);
3. Record of the Applicant;
4. Ability of the Applicant to Complete the Project.

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Due to the increasing number of opioid deaths in South Carolina, additional facilities are needed for the services to be accessible within thirty (30) minutes' travel time for the majority of state residents. The benefits of improved accessibility will ~~not~~ outweigh the adverse effects of the duplication of this existing service.

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CHAPTER VII

RESIDENTIAL TREATMENT FACILITIES FOR CHILDREN AND ADOLESCENTS

A Residential Treatment Facility for Children and Adolescents (RTF) is operated for the assessment, diagnosis, treatment, and care of two or more children and/or adolescents in need of mental health treatment. Children and/or adolescents up to age 21 who manifest a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree their capacity either to develop or to exercise age-appropriate or age-adequate behavior are treated by these facilities. ~~The behaviors treated include, but are not limited to, marked disorders of mood or thought processes, severe difficulties with self-control and judgment, including behavior dangerous to self or others, and serious disturbances in the ability to care for and relate to others.~~

These facilities provide medium to long-term care (six months or longer). Treatment modalities are both medical and behavioral in nature. Some facilities contract with the [South Carolina Continuum of Care \(COC\)](#) to provide these services.

Services available, at a minimum, should include the following:

1. 24-hour, awake supervision in a secure facility;
2. individual treatment plans to assess the problems and determine specific patient goals;
3. psychiatric consultation and professional psychological services for treatment supervision and consultation;
4. nursing services, as required;
5. regularly scheduled individual, group, and/or family counseling in keeping with the needs of each client;
6. recreational facilities with an organized youth development program;
7. a special education program with a minimum program defined by the South Carolina Department of Education; and
8. discharge planning including a final assessment of the patient's condition and an aftercare plan indicating any referrals to follow-up treatment and self-help groups.

Each facility shall have a written plan for cooperation with other public and private

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organizations, such as schools, social service agencies, etc., to ensure that each child under its care will receive comprehensive treatment. In addition, each facility shall have a written transfer agreement with one or more hospitals for the transfer of emergency cases when such hospitalization becomes necessary.

A proposal for Residential Treatment Facilities for Children and Adolescents should have letters of support from the Department of Social Services (DSS), DMH, and COC. ~~Priority consideration will be given to those facilities that propose to serve highly aggressive and sexual offending youths and those with other needs as determined by these State agencies. In addition, smaller facilities may be given greater consideration than large facilities based on recommendations from the above agencies.~~

The [Residential Treatment Facilities for Children & Adolescents Chart](#) is located ~~in Chapter XIII of this Plan at the end of this Chapter.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

~~1. The establishment or expansion of an RTF requires a Certificate of Need, unless the Department of Health and Human Services (DHHS) designates the facility as an existing high management group home (HMGH) or similar program.~~

~~1-2. Need projections are calculated by service area. The RTF service areas mirror the psychiatric service and inpatient drug and alcohol abuse service areas (i.e., Anderson/Oconee, Greenville/Pickens, etc.) to facilitate planning in a consistent manner.~~

~~2-3.~~ The applicant must document the need for the expansion of or the addition of an RTF based on the most current utilization data available. The existing resources must be considered and documentation presented as to why these resources are not adequate to meet the needs of the community.

~~3-4.~~ An existing facility that can demonstrate a 70% or greater occupancy rate for the most recent year prior can apply to add up to 5 additional beds, regardless of whether there is a bed need in the region.

~~4-5.~~ For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. For the expansion of an existing facility, the applicant must provide patient origin information on the current facility.

~~5-6.~~ The applicant must document the potential impact that the proposed new RTF or expansion will have upon the existing service providers and referral patterns.

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~~6-7.~~ The applicant must provide a written commitment that the facility will provide services for indigent and charity patients at a percentage that is comparable to other health care facilities in the service area.

~~7-8.~~ The applicant agrees to provide utilization data on the operation of the facility to the Department.

The bed need methodology to be used in South Carolina is based upon a standard of 41.4 beds per 100,000 children. Since few, if any, children under 5 years of age would be candidates for this type of care, the bed need will be based on the population age 5-21.

The [Projected Bed Need for Residential Treatment Facilities for Children & Adolescents Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

~~1. Compliance with the Need Outlined in this Section of the Plan;~~

~~1. Community Need Documentation;~~

2. Distribution (Accessibility);

~~3. Projected Revenues;~~

~~4-3. Projected Expenses~~ Medically Underserved Groups;

~~5-4.~~ Record of the Applicant; and

~~6. Ability of the Applicant to Complete the Project;~~

~~7-5. Cost Containment; and~~

~~8-6.~~ Staff Resources.

Residential treatment facility beds for children and adolescents are distributed statewide and are located within sixty (60) ~~minutes~~ minutes' travel time for the majority of residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

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CHAPTER VIII

CARDIOVASCULAR CARE¹

Diseases of the heart were responsible for as many deaths in South Carolina as cancer during 2013. Annually, heart disease and stroke are the leading cause of death in the State. Approximately one-third of all heart attacks are fatal. The amount of heart muscle damaged during a heart attack is an important determinant of whether patients live or die – and what their quality of life will be if they survive.

Diagnostic and therapeutic cardiac catheterizations and open heart surgery are tools in the treatment of heart disease. During a cardiac catheterization, a thin, flexible tube is inserted into a blood vessel in the arm or leg. The physician manipulates the tube to the chambers or vessels of the heart so that pressure measurements, blood samples and photographs can be taken. Injections of contrast material allow blockages or areas of weakness to appear on x-rays. Other diagnostic and therapeutic procedures may also be performed.

Percutaneous Coronary Interventions (PCIs) are therapeutic catheterization procedures used to revascularize occluded or partially occluded coronary arteries. These interventions include, but are not limited to: bare and drug-eluting stent implantation; Percutaneous Transluminal Coronary Angioplasty (PTCA); cutting balloon atherectomy; rotational atherectomy; directional atherectomy; excimer laser angioplasty; and extractional thrombectomy.

These procedures may be performed on an emergent or elective basis. “Emergent or Primary” means that a patient needs immediate PCI because, in the treating physician’s best clinical judgment, delay would result in undue harm or risk to the patient. An “Elective” PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure.

In 2011, the American College of Cardiology (ACC) and the American Heart Association (AHA) revised their Guidelines for PCI. The previous version of the Guidelines allowed the provision of Emergent/Primary PCIs in hospitals without an on-site open heart surgery program if certain criteria could be met, but, due to the risk of arterial damage and the resulting need for immediate open heart surgery, elective PCI was contraindicated for institutions without on-site surgical backup. The new Guidelines state that: Current guidelines issued by the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology (ACC), and the American Heart Association (AHA) allow for Emergent/Primary PCI as well as Elective PCI in facilities without

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¹ Due to the October 1, 2015, transition from ICD-9 to ICD-10 coding for medical diagnoses and inpatient hospital procedures, all ICD-9 codes referenced in the South Carolina Health Plan shall be deemed to refer to the corresponding ICD-10 codes, as determined by CMS, once this transition takes place.

~~on-site open heart surgery backup.~~

~~Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer.~~

Hospitals without an open heart surgery program shall be allowed to provide Emergent/Primary and/or Elective PCIs only if they comply with all sections of Standard 7 or 8 of the Standards for Cardiac Catheterization.

In 2013, ~~the Society of Cardiovascular Angiography and Interventions (SCAI)~~SCAI, ~~AHA/ACC~~ACC, and ~~ACC/AHA~~AHA updated their joint statement on clinical competence regarding coronary artery intervention procedures. The joint statement defined certain requirements for PCI operator competence and PCI facility volume requirements. The statement also noted an overall decrease in PCI volumes. ~~This statement does not contain a material change in the Plan's existing Certificate of Need requirements.~~

~~Open heart surgery or cardiac surgery refers to an operation performed on the heart or intrathoracic great vessels. The operations include Coronary Artery Bypass Graft (CABG), where veins are extracted from the patient and grafted to bypass a constricted section of coronary artery, and Minimally Invasive Direct Coronary Artery Bypass (MIDCAB), where the surgeon operates through a smaller incision rather than breaking the breastbone to open the chest cavity and no bypass machine is used.~~

Both cardiac catheterization and open heart surgery programs require highly skilled staffs and expensive equipment. Appropriately equipped and staffed programs serving larger populations are preferable to multiple, minimum population programs. Underutilized programs may reflect unnecessary duplication of services in an area, which may seriously compromise quality and safety of procedures and increase the cost of care. Optimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff. Cardiac catheterization laboratories should perform a minimum of ~~500-350 diagnostic equivalents per year (diagnostic catheterizations are weighted as 1.0 equivalents, therapeutic catheterizations as 2.0) procedures per year.~~ Emergent PCI ~~providers/operators~~ should perform a minimum of 36 PCIs annually; all other ~~therapeutic catheterization providers~~PCI operators should perform a minimum of ~~300-200 combined therapeutic catheterizations/procedures~~ annually. ~~Individual providers should perform a minimum of 50 PCIs annually (averaged over two years), including no less than 11 emergent/primary PCIs annually. It is recommended these be performed in facilities meeting a 200 procedure-per-year threshold. For pediatric catheterization and adult congenital catheterization labs, diagnostic catheterizations are weighted as 2.0 equivalents, therapeutic catheterizations as~~

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3.0, EP studies as 2.0, biopsies performed after heart transplants as 1.0 equivalents, and adult concomitant congenital heart disease procedures performed in these labs are included in the utilization calculations. A minimum of 150 procedures per year is recommended; half of these should be on neonates or infants. There should be a minimum of 200 adult open heart surgery procedures performed annually per open heart surgery unit; improved results appear to occur in hospitals that perform a minimum of 350 cases annually. Pediatric open heart surgery units should perform 100 pediatric heart operations per year, at least 75 of which should be open heart surgery.

CARDIAC CATHETERIZATION

Relevant Definitions

“[Cardiac Catheterization Procedure](#)” is an invasive procedure where a thin, flexible catheter is inserted into a blood vessel; the physician then manipulates the free end of the catheter into the chambers or vessels of the heart. All activities performed during one clinical session, including angiocardiography, coronary arteriography, pulmonary arteriography, coronary angioplasty and other diagnostic or therapeutic measures and physiologic studies shall be considered one procedure.

“[Comprehensive Catheterization Laboratory](#)” means a dedicated room or suite of rooms in which PCIs as well as diagnostic and therapeutic catheterizations are performed, in a facility with on-site open heart surgery backup.

“[Diagnostic Catheterization](#)” refers to a cardiac catheterization during which any or all of the following diagnostic procedures or measures are performed: Blood Pressure; Oxygen Content and Flow Measurements; Angiocardiography, Coronary Arteriography; and Pulmonary Arteriography. The following ~~ICD-9-CM~~[ICD-10-PCS](#) Procedure Codes refer to diagnostic catheterizations:

~~37.214A023N6~~ [Cardiac Sampling and Pressure, Right Heart, Percutaneous Approach](#)~~Right Heart Cardiac Catheterization~~

~~37.224A023N7~~ [Cardiac Sampling and Pressure, Left Heart, Percutaneous Approach](#)~~Left Heart Cardiac Catheterization~~

~~37.234A023N8~~ [Cardiac Sampling and Pressure, Bilateral, Percutaneous Approach](#)~~Combined Right and Left Heart Cardiac Catheterization~~

Additional clinical interpretation of Procedure Codes may be necessary to ensure appropriate conversions from ICD-9-CM to the new ICD-10-PCS.

▲ “[Diagnostic Catheterization Laboratory](#)” means a dedicated room in which only diagnostic catheterizations are performed.

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"Percutaneous Coronary Intervention (PCI)" refers to a therapeutic procedure to relieve coronary narrowing, such as Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Stent Implantation. These procedures may be performed on an emergent or elective basis. "Emergent or Primary" means that a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. An "Elective" PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure.

"Therapeutic Catheterization" refers to a PCI or cardiac catheterization during which, in addition to any diagnostic catheterization procedure, any or all of the following interventional procedures are performed: PTCA; Thrombolytic Agent Infusion; Directional Coronary Atherectomy; Rotational Atherectomy; Extraction Atherectomy; Coronary Stent Implants and Cardiac Valvuloplasty. The following ~~ICD-9-CM~~ICD-10-PCS Procedure Codes refer to therapeutic catheterizations:

~~00.66 02703ZZ and related Dilation of Coronary Artery, One Artery, Percutaneous Approach~~Percutaneous Transluminal Coronary Angioplasty (PTCA)

~~47.55 02C03ZZ~~ Extirpation of Matter from Coronary Artery, One Artery, Percutaneous Approach~~Transluminal Coronary Atherectomy~~

~~35.52 02U53JZ~~ Supplement Atrial Septum with Synthetic Substitute, Percutaneous Approach~~Repair of Atrial Septal Defect with Prosthesis, Closed Technique~~

~~35.55 02RM4JZ~~ Replacement of Ventricular Septum with Synthetic Substitute, Percutaneous Endoscopic Approach~~Repair of Ventricular Septal Defect with Prosthesis, Closed Technique~~

~~35.96 027F3ZZ and related Dilation of Aortic Valve, Percutaneous Approach~~Percutaneous Valvuloplasty

~~36.06 02703DZ~~ Insertion of Non-Drug Eluting Coronary Artery Stent(s)

~~36.07 027034Z~~ Insertion of Drug Eluting Coronary Artery Stent(s)

~~36.09 02C03ZZ and related Extirpation of Matter from Coronary Artery, One Artery, Percutaneous Approach~~Other Removal of Coronary Artery Obstruction

~~37.34 02563ZZ and related Destruction of Right Atrium, Percutaneous Approach~~Excision or Destruction of Other Lesion or Tissue of Heart, Endovascular Approach

Additional clinical interpretation of Procedure Codes may be necessary to ensure appropriate conversions from ICD-9-CM to the new ICD-10-PCS.

Scope of Services

The following services should be available in both adult and pediatric catheterization laboratories:

1. Each cardiac catheterization lab should be competent to provide a range of

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angiographic (angiocardiography, coronary arteriography, pulmonary arteriography), hemodynamic, and physiologic (cardiac output measurement, intracardiac pressure, etc.) studies. These facilities should be available in one laboratory so that the patient need not be moved during a procedure.

2. The lab should have the capability of immediate endocardiac catheter pacemaking in cardiac arrest, a crash cart, and defibrillator.
3. A full range of non-invasive cardiac/circulatory diagnostic support services, such as the following, should be available within the hospital:
 - a. Nuclear Cardiology
 - b. Echocardiography
 - c. Pulmonary Function Testing
 - d. Exercise Testing
 - e. Electrocardiography
 - f. Cardiac Chest X-ray and Cardiac Fluoroscopy
 - g. Clinical Pathology and Blood Chemistry Analysis
 - h. Phonocardiography
 - i. Coronary Care Units (CCUs)
 - j. Medical Telemetry/Progressive Care
4. Each applicant shall document plans for providing cardiac rehabilitation services to its patients or plans for establishing referral agreements with facilities offering cardiac rehabilitation services.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The capacity of a fixed cardiac catheterization laboratory shall be 1,200 ~~diagnostic equivalents~~ procedures per year, as measured on an equivalent basis. ~~Adult diagnostic catheterizations shall be weighted as 1.0 equivalents, while therapeutic catheterizations shall be weighted as 2.0 equivalents. Each adult cardiac catheterization shall carry a weight of 1.0 procedures, while each adult therapeutic catheterization performed in the fixed laboratory shall carry a weight of 2.0 procedures.~~ For pediatric and adult congenital catheterization labs, diagnostic catheterizations shall ~~be weighted as 2.0 equivalents~~ carry the weight of 2.0 procedures, therapeutic catheterizations shall ~~be weighted as 3.0 equivalents~~ carry the weight of 3.0 procedures, electrophysiology (EP) studies shall ~~be weighted as~~ carry the weight of 2.0 ~~equivalents~~ procedures, and biopsies performed after heart transplants shall ~~be weighted as 1.0 equivalents~~ carry the weight of 1.0 procedures. The capacity of mobile cardiac catheterization labs will be calculated based on the number of days of operation per week.

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2. The service area for a diagnostic catheterization laboratory is defined as all facilities within ~~45-30 minutes~~ minutes, ~~one-way automobile travel~~ emergency medical transport time; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes' ~~one-way automobile travel~~ emergency medical transport time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.

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Diagnostic and Mobile Catheterization Services

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of ~~500-350~~ diagnostic catheterization procedures per laboratory during the most recent year;
4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of ~~500-350 diagnostic equivalent~~ procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below ~~500-350~~ diagnostic cardiac catheterization procedures per laboratory.
5. Expansion of an existing diagnostic catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (i.e., 960 ~~equivalents per laboratory~~ procedures by equivalent measure) for each of the past two years and can project a minimum of ~~500-350~~ procedures per year on the additional equipment within three years of its implementation.
6. An applicant for a mobile diagnostic catheterization laboratory must be able to project a minimum of ~~400-75~~ diagnostic ~~equivalents procedures~~ annually for each day of the week that the mobile lab is located at the applicant's facility by the end of the third year following initiation of the service, without reducing the utilization of the existing diagnostic catheterization services in the service area below ~~500-350~~ diagnostic catheterization procedures per laboratory (i.e., an applicant wishing to have a mobile catheterization lab 2 days per week must project a minimum of 200 equivalents at the applicant's facility by the end of the third year of operation). In addition:
- a. The applicant must document that the specific mobile unit utilized by the vendor will perform a combined minimum of ~~500-350 diagnostic equivalents procedures~~ per year;
- b. The applicant must include vendor documentation of the complication rate of the mobile units operated by the vendor; and

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- c. If an application for a mobile lab is approved and the applicant subsequently desires to change vendors, the Department must approve such change in order to insure that appropriate minimum utilization can be documented.

Emergent and Elective PCI without On-Site Cardiac Backup

- 7. ~~In 2005, the ACCF/AHA/SCAI Writing Committee determined that Emergency PCI (Primary PCI) is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.~~ Hospitals with diagnostic laboratories may be approved to perform emergency PCI without an on-site open heart surgery program only if all of the following criteria ~~based on the 2005 ACC/AHA Guideline Update for PCI~~ are met:

- a. Therapeutic catheterizations must be limited to Percutaneous Coronary Interventions (PCIs) performed only in emergent circumstances (Primary PCIs). Elective PCI may not be performed at institutions that do not provide on-site cardiac surgery except as provided for in Standard 8 below.

- b. The applicant has performed a minimum of ~~250~~350 diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will continue to perform a minimum of ~~500~~350 diagnostic catheterizations annually within three years of the initiation of services.

- c. The hospital must acquire an intra-aortic balloon pump (IABP) dedicated solely to this purpose.

- d. The chief executive officer of the hospital must sign an affidavit assuring that ~~the criteria listed~~the current guidelines mentioned below are and will continue to be met at all times.

- e. ~~An application shall be approved only if it is consistent with the current criteria from Smith et al., ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACCF/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention) and the 2007 Focused Update of the guidelines established by SCAI/ACC/AHA as they appear at the time an application for a CON is filed under this Chapter.~~ A complete copy of the current guidelines can be found at: www.acc.org/clinical/guidelines/percutaneous/update/index.pdf.

- e.f. ~~An applicant for provision of emergent/primary PCI without on-site surgical backup agrees, as a condition for issuance of its Certificate of Need for such~~

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service, to discontinue such services and surrender the Certificate of Need for that service if they have failed to achieve 350 diagnostic catheterizations per year by the expiration of the first three years of operation of such services.

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1) ~~Criteria for the Performance of Emergency (Primary) PCI:~~

- ~~a) The physicians must be experienced interventionalists who regularly perform elective intervention at a surgical center (75 cases/year). The institution must perform a minimum of 36 primary PCI procedures per year.~~
- ~~b) The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hour, 365-day call schedule.~~
- ~~c) The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.~~
- ~~d) The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.~~
- ~~e) The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.~~
- ~~f) There must be formalized written protocols in place for immediate (within one hour) and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed/tested on a regular (quarterly) basis.~~
- ~~g) Primary (emergency) intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction (AMI) to ensure streamlined care paths and increased case volumes.~~
- ~~h) Case selection for the performance of primary (emergency) angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary (emergency) angioplasty and for the selection for transfer for emergent aortocoronary bypass surgery are shown in Section E.2.~~
- ~~i) There must be an ongoing program of outcomes analysis and formalized periodic case review. Institutions should participate in a three-to-six month period of implementation during which time development of a formalized primary PCI program is instituted that includes establishing standards, training staff, detailed logistic development, and creation of a quality assessment and error management system.~~

2) Patient Selection Guidelines

a) Avoid intervention in hemodynamically stable patients with:

- (1) Significant (60%) stenosis of an unprotected left main (LM) coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.
- (2) Extremely long or angulated infarct-related lesions with TIMI grade 3 flow.
- (3) Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease.
- (4) Infarct-related lesions of small or secondary vessels.
- (5) Lesions in other than the infarct artery.

b) Transfer emergent aortocoronary bypass surgery patients after PCI of occluded vessels if high-grade residual left main or multi-vessel coronary disease and clinical or hemodynamic instability are present, preferably with intra-aortic balloon pump support.

8. In ~~2011~~2014, the ~~ACCF/AHA/SCAI Writing Committee~~SCAI/ACC/AHA determined affirmed that elective PCI ~~might be considered~~may be safely performed in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. Hospitals with diagnostic laboratories that have been approved to perform primary PCI without on-site open heart surgical backup ~~under the 2005 ACC/AHA Guideline Update for PCI~~ must obtain a Certificate of Need in order to upgrade to a designation as providing elective PCI without on-site cardiac surgery backup. The following standards must be met:

- a. The applicant has performed a minimum of ~~250-350~~ diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will ~~continue to~~ perform a minimum of ~~500-350~~ diagnostic catheterizations annually within three years of the initiation of services.
- b. All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of ~~300-200~~ therapeutic catheterizations (PCIs) in the most recent year.
- c. An applicant must project that the proposed service will perform a minimum of ~~300-200~~ therapeutic catheterization procedures annually within three years of initiation of services, without reducing the cardiac catheterizations

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performed at existing comprehensive catheterization programs in the service area below the minimum thresholds of ~~300-200~~ therapeutic procedures and ~~500-350~~ diagnostic procedures at each facility.

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- d. The physicians must be experienced ~~interventionalists~~~~interventionists~~ who perform a minimum of ~~75-50~~ elective PCI cases per year and preferably at least 11 PCI procedures for STEMI each year. Ideally, operators with an annual procedure volume of fewer than ~~75-50~~ procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than ~~75-50~~ procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures.

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- e. For catheterization labs in facilities without on-site surgical backup, there must be formalized written protocols in place for immediate ~~(within one hour by appropriate transportation)~~ emergency transport beginning with 30 minutes and arriving at surgical facility within 60 minutes and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed and tested on a regular basis.

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– Applicants must provide documentation of an agreement with an ambulance or transport service capable of advanced life support and intra-aortic balloon pump and that guarantees a thirty (30) minute or less response time from contact.

- f. The catheterization laboratory must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.
- g. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hour, 365-day call schedule.
- h. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
- i. Applicants must offer primary percutaneous coronary intervention (PCI) services and procedures twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty five (365) days a year.

- j. Applicants must provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with standards of the American College of Cardiology have been developed and will be maintained.
- k. Applicants must agree to participate in the South Carolina STEMI Mission Lifeline Program.
- l. Every therapeutic catheterization program should operate a quality-improvement program that routinely:
 - 1) reviews quality and outcomes of the entire program;
 - 2) reviews results of individual operators;
 - 3) includes risk adjustment;
 - 4) provides peer review of difficult or complicated cases; and
 - 5) performs random case reviews.
- m. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms.
- n. An applicant for provision of elective PCI without on-site surgical backup agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue therapeutic catheterization services and surrender the Certificate of Need for that service if they have failed to achieve 200 therapeutic catheterizations (PCIs) per year by the expiration of the first three years of operation of such services.

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Comprehensive Catheterization Services

- 9. Comprehensive catheterization laboratories, which perform diagnostic catheterizations, PCI and other therapeutic procedures, shall only be located in hospitals that provide open heart surgery. New comprehensive cardiac catheterization services shall be approved only if the following conditions are met:
 - a. All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of ~~300-200~~ therapeutic catheterizations (PCIs) in the most recent year; and
 - b. An applicant must project that the proposed service will perform a minimum of ~~300-200~~ therapeutic catheterization procedures annually within three years of initiation of services, without reducing the therapeutic catheterizations performed at existing comprehensive catheterization programs in the service area below ~~300-200~~ procedures at each facility.

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10. To prevent the unnecessary duplication of comprehensive cardiac catheterization services, expansion of an existing comprehensive cardiac catheterization service shall be approved only if the service has operated at a minimum use rate of 80% of capacity (960 equivalents per lab) for each of the past two years and can project a minimum of 600 ~~equivalents-procedures, as measured on an equivalent basis,~~ per year on the additional equipment within three years of its implementation. The 600 equivalents may consist of a combination of diagnostic and therapeutic procedures.

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Pediatric Catheterization Services

11. New pediatric cardiac catheterization services shall be approved only if the following conditions are met:
- All existing facilities have performed at a combined use rate of 80% of capacity for the most recent year; and
 - An applicant must project that the proposed service will perform a minimum of 500 ~~diagnostic-equivalent-procedures, as measured on an equivalent basis,~~ annually within three years of initiation of services.
12. Expansion of an existing pediatric cardiac catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (960 equivalents) for each of the past two years and can project a minimum of 500 ~~equivalents-procedures~~ per year, ~~as measured on an equivalent basis,~~ on the additional equipment within three years of its implementation.
13. Documentation of need for the proposed service:
- The applicant shall provide epidemiologic evidence of the incidence and prevalence of conditions for which diagnostic, comprehensive or pediatric catheterization is appropriate within the proposed service area, to include the number of potential candidates for these procedures;
 - The applicant shall project the utilization of the service and the effect of its projected utilization on other cardiac catheterization services within its service area, to include:
 - 1) The number of patients of the applicant hospital who were referred to other cardiac catheterization services in the preceding three years and the number of those patients who could have been served by the proposed service;

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2) The number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians, or other changes in circumstances. The applicant shall document the services, if any, from which these patients will be drawn; and

3) Existing and projected patient origin information and referral patterns for each cardiac catheterization service serving patients from the area proposed to be served shall be provided.

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14. Both fixed and mobile diagnostic cardiac catheterization laboratories must provide a written agreement with at least one hospital providing open heart surgery, which states specified arrangements for referral and transfer of patients, to include:

- a. Criteria for referral of patients on both a routine and an emergency back-up basis;
- b. Regular communications between cardiologists performing catheterizations and surgeons to whom patients are referred;
- c. Acceptability of diagnostic results from the cardiac catheterization service to the receiving surgical service to the greatest extent possible to prevent duplication of services; and
- d. Development of linkages with the receiving institution's peer review mechanism.

15. The application shall include standards adopted or to be adopted by the service, consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, defining high-risk procedures and patients who, because of their conditions, are at high risk. For diagnostic catheterization laboratories, this description of patient selection criteria shall include referral arrangements for high-risk patients. For comprehensive laboratories, these high-risk procedures should only be performed with open heart surgery back-up. The cardiac team must be promptly available and capable of successfully operating on unstable acute ischemic patients in an emergency setting.

16. Cardiac catheterization services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform diagnostic, therapeutic and/or pediatric catheterizations. Applicants must provide documentation that one (1) or more interventional cardiologist(s) will be required to

respond to a call in a timely manner consistent with the hospital Medical Staff bylaws and clinical indications. In addition, standards should be established to assure that each physician using the service would be involved in adequate numbers of applicable types of cardiac catheterization procedures to maintain proficiency.

17. Applicants must agree to report annual the data on number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cat/PCI registry.
 - a. Applicants must agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review by appropriate entities.
 - b. The Department encourages all applicants and providers to share their outcomes data with appropriate registries and research studies designed to improve the quality of cardiac care.

The [Cardiac Catheterization Procedures Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- ~~1. Compliance with the Need Outlined in this Section of the Plan;~~
- ~~2.1. Community Need Documentation;~~
- ~~3.2. Distribution (Accessibility);~~
- ~~4. Projected Revenues;~~
- ~~5. Projected Expenses;~~
- ~~6.3. Ability of the Applicant to Complete the Project;~~
- ~~7.4. Financial Feasibility; Medically Underserved Groups;~~
- ~~8.5. Staff Resources;~~
- ~~9.6. Adverse Effects on Other Facilities; and~~
- ~~10.7. Record of the Applicant.~~

The Department finds that:

- (1) Diagnostic catheterization services are ~~generally~~ available within forty-five (45) ~~minutes~~ ~~minutes~~, and therapeutic catheterization services within ninety (90) ~~minutes~~ ~~minutes~~ travel time for the majority of South Carolina residents;
- (2) Significant cardiac catheterization capacity exists in most areas of the State; and

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- (3) The preponderance of the literature on the subject indicates that a minimum number of procedures are recommended per year in order to develop and maintain physician and staff competency in performing these procedures.

The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

OPEN HEART SURGERY

Relevant Definitions

[“Open Heart Surgery”](#) refers to an operation performed on the heart or intrathoracic great vessels. It is identified by the following ICD-9-CM procedure codes: 35.10-35.14, 35.20-35.28, 35.31-35.35, 35.39, 35.41-35.42, 35.50-35.51, 35.53-35.54, 35.60- 35.63, 35.70-35.73, 35.81-35.84, 35.91-35.95, 35.98-35.99, 36.03, 36.09, 36.10-36.16, 36.19, 36.2, 36.91, 36.99, 37.10-37.11, 37.32-37.33.

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An [“Open Heart Surgery Unit”](#) is an operating room or suite of rooms equipped and staffed to perform open heart surgery procedures; such designation does not preclude its use for other related surgeries, such as vascular surgical procedures. A hospital with an open heart surgery program may have one or more open heart surgery units.

[“Open Heart Surgical Procedure”](#) means an operation performed on the heart or intrathoracic great vessels within an open heart surgical unit. All activities performed during one clinical session shall be considered one procedure.

[“Open Heart Surgical Program”](#) means the combination of staff, equipment, physical space and support services used to perform open heart surgery. Adult open heart surgical programs should have the capacity to perform a full range of procedures, including:

1. repair/replacement of heart valves
2. repair of congenital defects
3. cardiac revascularization
4. repair/reconstruction of intrathoracic vessels
5. treatment of cardiac traumas

In addition, open heart programs must have the ability to implement and apply circulatory assist devices such as intra-aortic balloon and prolonged cardiopulmonary partial bypass.

Scope of Services

A range of non-invasive cardiac and circulatory diagnostic services should be available within the hospital, including the following:

1. services for hematology and coagulation disorders
2. electrocardiography, including exercise stress testing
3. diagnostic radiology
4. clinical pathology services which include blood chemistry and blood gas analysis
5. nuclear medicine services which include nuclear cardiology
6. echocardiography
7. pulmonary function testing
8. microbiology studies
9. Coronary Care Units (CCU's)
10. medical telemetry/progressive care
11. perfusion

Backup physician personnel in the following specialties should be available in emergency situations:

1. cardiology
2. anesthesiology
3. pathology
4. thoracic surgery
5. radiology

Each applicant shall document plans for providing cardiac rehabilitation services to its patients or plans for establishing referral agreements with facilities offering cardiac rehabilitation services.

Adult open heart surgery services should be available within 60 ~~minutes~~^{minutes'} one-way automobile travel for 90% of the population. A pediatric cardiac surgical service should provide services for a minimum service area population with 30,000 live births, or roughly 2 million people. Open heart surgery for elective procedures should be available at least 40 hours per week, and elective open heart surgery should be accessible with a waiting time of no more than two weeks. All facilities providing open heart surgery must conform to local, state, and federal regulatory requirements and should meet the full accreditation standards for The Joint Commission (TJC), if the facility is TJC accredited.

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

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1. ~~The establishment or addition of an open heart surgery unit-program requires Certificate of Need review, as this is considered a substantial expansion of a health service.~~
2. Comprehensive cardiac catheterization laboratories shall only be located in hospitals that provide open heart surgery.

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3. The capacity of an open heart surgery program is 500 open heart procedures per year ~~for the initial open heart surgery unit and each additional dedicated per~~ open heart surgery unit (*i.e.*, each operating room equipped and staffed to perform open heart surgery has a maximum capacity of 500 procedures annually).

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4. There should be a minimum of 200 adult open heart surgery procedures performed annually per open heart surgery unit within three years after initiation in any institution in which open heart surgery is performed for adults. In institutions performing pediatric open heart surgery there should be a minimum of 100 pediatric heart operations per open heart surgery unit; at least 75 should be open heart surgery.

5. New open heart surgery services shall be approved only if the following conditions are met:

a. Each existing unit in the service area (defined as all facilities within 60 ~~minutes~~ minutes" one way automobile travel, excluding any facilities located in either North Carolina or Georgia) is performing an annual minimum of 350 open heart surgery procedures per open heart surgery unit for adult services (70 percent of functional capacity). The standard for pediatric open heart cases in pediatric services is 130 procedures per unit. An exception to this requirement may be authorized should an applicant meet both of the following criteria:

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1) There are no open heart surgery programs located in the same county as the applicant; and

2) The proposed facility currently offers cardiac catheterization services and provided a minimum of 1,200 diagnostic ~~equivalents procedures,~~ as measured on an equivalent basis, in the previous year of operation.

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b. An applicant must project that the proposed service will perform a minimum of 200 adult open heart surgery procedures annually per open heart surgery unit within three years after initiation (the standard for pediatric open heart surgery shall be 100 procedures annually per open heart surgery unit within three years after initiation):

1) The applicant shall provide epidemiological evidence of the incidence and prevalence of conditions for which open heart surgery is appropriate within the proposed service area, to include the number of potential candidates for these procedures;

2) The applicant shall provide an explanation of how the applicant

projects the utilization of the service and the effect of its projected utilization on other open heart surgery services, including:

- a) The number of patients of the applicant hospital who were referred to other open heart surgery services in the preceding three years and the number of these patients who could have been served by the proposed service;
 - b) The number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians, or other changes in circumstances. The applicant shall document the services, if any, from which these patients will be drawn; and
 - c) The existing and projected patient origin information and referral patterns for each open heart surgery service serving patients from the area proposed to be served shall be provided.
6. No new open heart surgery programs shall be approved if the new program will cause the annual caseload of other programs within the proposed service area to drop below 350 adult procedures or 130 pediatric procedures per open heart surgery unit.
7. An incremental expansion of one open heart surgery unit shall not be grounds for Certificate of Need review. Expansion of an existing open heart surgery service beyond the incremental increase of one open heart unit shall only be approved if the service has operated at a minimum use rate of 70 percent of capacity for each of the past two years and can project a minimum of 200 procedures per year in the new open heart surgery unit. The applicant shall document the other service providers, if any, from which these additional patients will be drawn.
8. The application shall include standards adopted or to be adopted by the service, consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, defining high-risk procedures and patients who, because of their conditions, are at high risk and shall state whether high-risk cases are or will be performed or high-risk patients will be served.
9. Open heart surgery services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform open heart surgery and therapeutic cardiac catheterizations. In addition, standards should be established to assure that each physician using the service will be involved in

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adequate numbers of applicable types of open heart surgery and therapeutic cardiac catheterizations to maintain proficiency.

10. The open heart surgery service will have the capability for emergency coronary artery surgery, including:

- a. Sufficient personnel and facilities available to conduct the coronary artery surgery on an immediate, emergency basis, 24 hours a day, 7 days a week;
- b. Location of the cardiac catheterization laboratory(ies) in which therapeutic catheterizations will be performed near the open heart surgery operating rooms; and
- c. A predetermined protocol adopted by the cardiac catheterization service governing the provision of percutaneous transluminal coronary angioplasty (PTCA) and other therapeutic or high-risk cardiac catheterization procedures or the catheterization of patients at high risk and defining the plans for the patients' emergency care. These high-risk procedures should only be performed with open heart surgery backup. The cardiac team must be promptly available and capable of successfully operating on unstable acute ischemic patients in an emergency setting.

11. The Department encourages all applicants and providers to share their outcomes data with appropriate registries and research studies designed to improve the quality of cardiac care.

12. An applicant for open heart surgery service agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue services and surrender the Certificate of Need for that service if they have failed to achieve 200 open heart procedures per open heart unit per year by the expiration of the first three years of operation of such services. Incremental expansions of one open heart unit are subject to the same threshold, and any such unit shall be closed if it does not achieve 200 open heart procedures within three years of the expansion.

The expansion of an existing open heart surgery service shall only be approved if the service has operated at a minimum use rate of 70 percent of capacity for each of the past two years and can project a minimum of 200 procedures per year in the new open heart surgery unit. The applicant shall document the other service providers, if any, from which these additional patients will be drawn.

11.

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The [Open Heart Units Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- ~~1. Compliance with the Need Outlined in this Section of the Plan;~~
- ~~2.1. Community Need Documentation;~~
- ~~3.2. Distribution (Accessibility);~~
- ~~4. Projected Revenues;~~
- ~~5. Projected Expenses;~~
- ~~6.3. Ability of the Applicant to Complete the Project;~~
- ~~7.4. Financial Feasibility~~Record of the Applicant;
- ~~8.5. Cost Containment;~~
- ~~9.6. Staff Resources; and~~
- ~~10.7. Adverse Effects on Other Facilities.~~

The Department makes the following findings:

- (1) Open heart surgery services are available within sixty (60) ~~minutes~~ minutes' travel time for the majority of residents of South Carolina;
- (2) Based upon the standards cited above, most of the open heart surgery providers are currently utilizing less than the functional capability (*i.e.*, 70% of maximum capacity) of their existing surgical suites;
- (3) The preponderance of the literature on the subject indicates that a minimum number of procedures is recommended per year in order to develop and maintain physician and staff competency in performing these procedures; and
- (4) Increasing geographic access may create lower volumes in existing programs causing a potential reduction in quality and efficiency, exacerbate existing problems regarding the availability of nursing staff and other personnel, and not necessarily reduce waiting time since other factors (such as the referring physician's preference) would still need to be addressed.
- (5) Research has shown a positive relationship between the volume of open heart surgeries performed annually at a facility and patient outcomes. Thus, the Department establishes minimum standards that must be met by a hospital in order to provide open heart surgery. Specifically, a hospital is required to project a minimum of 200 open heart surgeries annually within three years of initiation of services. This number is considered to be the minimum caseload required to operate

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a program that maintains the skill and efficiency of hospital staff and reflects an efficient use of an expensive resource. It is in the public's interest that facilities achieve their projected volumes.

- (6) The Department recognizes the important correlation between volume and proficiency. The Department further recognizes that the number of open heart surgery cases is decreasing and that maintaining volume in programs is very important to the provision of quality care to the community.

The benefits of improved accessibility will not outweigh the adverse effects of duplication in evaluating Certificate of Need applications for this service.

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CHAPTER IX

RADIATION ONCOLOGY

Cancer is a group of related diseases that involve out-of-control growth and spread of abnormal cells. These cells accumulate and form tumors that invade and destroy normal tissue. The American Cancer Society (ACS) estimates that 1 in 2 men and 1 in 3 women will suffer from cancer during their lifetimes. The most common types of cancer include prostate cancer for men, breast and uterine cancer for women, whereas lung and colon cancer are a common occurrence in both genders. The Department tracks the occurrence of cancer in the State, including identification of “[cancer cluster](#)” locations, through the [South Carolina Central Cancer Registry](#). ~~The five-year survival rate in South Carolina for all persons diagnosed with cancer was 68% from 2003 to 2009. This was an increase from the 49% survival rate calculated for 1975-1977.~~

Megavoltage radiation has been utilized for decades as a standard modality for cancer treatment. It is best known as Radiation Therapy, but is also called Radiotherapy, X-Ray Therapy, or Irradiation. ~~It kills cancer cells and shrink tumors by damaging their genetic material, making it impossible for these cells to continue to grow and divide. Approximately 50% of all cancer patients receive radiation therapy at some time during their illness, either alone or in combination with surgery or chemotherapy. It can be used as a therapeutic treatment (to attempt to cure the disease), a prophylactic treatment (to prevent cancer cells from growing in the area receiving the radiation) or as a palliative treatment (to reduce suffering and improve quality of life when a cure is not possible).~~

Beams of ionizing radiation are aimed to meet at a specific point and deliver radiation to that precise location. The amount of radiation used is measured in “gray” (Gy) and varies depending on the type and stage of cancer being treated. Radiation damages both cancer cells and normal cells, so the goal is to damage as many cancer cells as possible, while limiting harm to nearby healthy tissue. A typical course of treatment lasts for two to ten weeks, depending on the type of cancer and the treatment goal.

Relevant Definitions

There are varying types of radiation treatment, and definitions are often used interchangeably. The following definitions apply:

[“Adaptive Radiation Therapy \(ART\)”](#) – Patient setup and/or radiation delivery is evaluated and modified periodically during the treatment course based on imaging and dose measurements made prior to or during treatment.

[“Conformal Radiation Therapy \(CRT\)”](#) – Since the target often has a complex shape, CT, MRI,

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or PET is used to create a 3-D image of the tumor. Using the image, the computer designs the radiation beams to be shaped exactly (conform) to the contour of the treatment area. This type of therapy is provided through a number of methods know by different names.

[“Electronic Portal Imaging Devices \(EPIDs\)”](#) have been developed because of the increased complexity of treatment planning and delivery techniques. The most common EPIDs are video-based systems wherein on-line digital port images are captured and analyzed before or during treatment. These systems are used for pre-treatment verification of Intensity Modulated Radiation Therapy fields and to reduce errors in patient positioning.

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[“Fractionation”](#) is the practice of providing only a small fraction of the entire prescribed dose of radiation in each treatment or session. Individual treatment plans are created to minimize the side effects for normal tissue. The typical fractionation schedule for adults is once per day, five days a week. Hyperfractionation (Superfractionation) refers to radiation given in smaller doses twice a day. In Hypofractionation, individual doses are given less often than daily, such as in two-five sessions.

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[“Image-Guided Radiation Therapy \(IGRT\)”](#) visualizes (by means of EPIDs, kV scans or mV scans) the patient’s anatomy during treatments. This allows for confirmation of beam location and adjustment of the beams if needed during treatments due to breathing. IGRT facilitates more accurate patient positioning and reduces healthy tissue damage.

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[“Intensity Modulated Radiation Therapy \(IMRT\)”](#) creates a 3-D radiation dose map to treat the tumor. It uses a multi-leaf collimator to modulate or control the outlines and intensity of the radiation field during cancer treatment. Due to its precision it can spare more healthy tissue, but it also requires detailed data collection and takes longer than conventional therapy.

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[“Stereotactic Body Radiation Therapy \(SBRT\)”](#) is a precision radiation therapy delivery concept derived from cranial stereotactic radiosurgery. It is characterized by one to five fraction delivery of focal high-dose radiation while limiting dose to surrounding normal tissues. SBRT has become an established treatment technique for lung, liver, and spinal lesions.

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[“Stereotactic Radiosurgery \(SRS\)”](#) is a single-session procedure used to treat brain tumors and other brain disorders that cannot be treated by regular surgery. The radiation dose given in one session is usually less than the total dose that would be given with radiation therapy. However, the tumor receives a very high one-time dose of radiation with radiosurgery versus smaller fractions over time with radiation therapy. It is also known as Stereotaxic Radiosurgery or Radiation Surgery.

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[“Stereotactic Radiation Therapy \(SRT\)”](#) is an approach similar to Stereotactic Radiosurgery that delivers radiation to the target tissue. However, the total dose of radiation is divided

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into several smaller doses given over several days, rather than a single large dose. The treatment time per session typically ranges from 30 to 90 ~~minutes~~minutes, for two-five sessions. It can be used to treat both brain and extracranial tumors.

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TYPES OF RADIATION EQUIPMENT

Particle Beam (Proton)

Particle beams use heavy charged subatomic particles to deliver radiation to the tumor. Most tumors could be cured with a sufficiently high dose of radiation; however, such a treatment is ineffective due to collateral damage to healthy tissue. Particle therapy can lessen the damage to healthy tissue by tailoring the particle (either a proton particle or a heavier carbon particle) dose to the tumor. Unfortunately, this promising treatment option is not readily available.

Linear Accelerator (X-Ray or LINAC)

The LINAC produces high energy x-rays that are collected to form a beam that matches the size and shape of the patient's tumor. Radiation can be delivered to the tumor from any angle by a rotating robotic arm. A LINAC must be located in a room with lead and concrete walls to keep the rays from escaping. A conventional LINAC requires modifications, such as additional equipment, in order to be used for IMRT or other advanced techniques.

Minimal equipment requirements for a linear accelerator include:

1. At least 1 teletherapy unit, with an energy exceeding 1 megavolt (MV); the distance from the source to the isocenter must be at least 80 cm.
2. Access to an electron beam source or a low energy X-ray unit.
3. Adequate equipment to calibrate and measure dosimetric characteristics of all treatment units in the department.
4. Capability to provide appropriate dose distribution information for external beam treatment.
5. Equipment for accurate simulation of the treatment units in the department (in general, one simulator can service 2-3 megavoltage treatment units).
6. Field-shaping capability.
7. Access to CT scanning capability.

The capacity standards for a linear accelerator vary by the capability of the equipment and

~~are addressed in the Standards below. A conventional linear accelerator, either with or without EPID, has a capacity of 7,000 treatments per year, based upon an average of 28 patients treated per day, 5 days per week, 50 weeks per year. LINACs with IMRT and IGRT systems (such as Tomotherapy and Novalis TX) take longer to set up and perform treatments than those relying on previously generated images. Therefore, a lower capacity of 5,000 treatments per year is established for such equipment (20 patients treated per day, 5 days per week, 50 weeks per year). IMRT/IGRT machines that perform stereotactic procedures have a lower capacity of 4,500 treatments per year (18 patients treated per day, 5 days per week, 50 weeks per year).~~

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There is also LINAC equipment designed strictly to provide Stereotactic Radiotherapy in 1-5 treatment sessions. These specialized LINACs have an even lower capacity because of the treatment time associated with this type of care. The capacity for such equipment is established as 1,500 treatments per year per unit, ~~based on 6 treatments per day, 5 days per week, for 50 days per year. The Cyberknife is the only equipment so designated. It is an older generation unit with a previously designated capacity of 1,000 treatments per year. The capacity and need calculations for this facility and service area have also been adjusted.~~

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Cobalt-60 (Photon)

This modality, best known by the trade name of Gamma Knife, is used to perform Stereotactic Radiosurgery. It is primarily used to treat brain tumors, although it can also be used for other neurological conditions like Parkinson's Disease and Epilepsy. Its use is generally reserved for cancers that are difficult or dangerous to treat with surgery. The radiation damages the genetic code of the tumor in a single treatment, preventing it from replicating and causing it to slowly shrink.

The Gamma Knife consists of a large shield surrounding a large helmet-shaped device with separate, fixed ports that allow the radiation to enter the patient's head in small beams that converge on the designated target. A rigid frame is attached to the patient's skull to provide a solid reference for both targeting and treatment. The patient is then sent for imaging, to accurately determine the position of the target. The computer system develops a treatment plan to position the patient and the paths and doses of radiation. The patient is positioned with the head affixed to the couch, and the treatment is delivered.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS FOR RADIOTHERAPY

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1. The capacity of a conventional linear accelerator, either with or without EPID, is 7,000 treatments per year.
2. Linear accelerators providing IMRT or IGRT have a capacity of 5,000 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning

capacity.

3. IMRT/IGRT linear accelerators performing stereotactic procedures have a capacity of 4,500 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.
4. Linear Accelerators designed strictly to provide Stereotactic Radiotherapy have a capacity of 1,500 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.
5. There are 13 service areas established for Radiotherapy units.
6. New Radiotherapy services shall only be approved if the following conditions are met:
 - a. All existing units in the service area have performed at a combined use rate of 80 percent of capacity for the year immediately preceding the filing of the applicant's Certificate of Need application; and
 - b. An applicant must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold. If the new equipment is a specialized radiotherapy unit as described in Standards 2, 3 or 4 above, then the applicant may propose an annual capacity based on the specialized use of the equipment by that applicant. If the applicant can justify this proposed annual capacity, then this capacity will be used in Certificate of Need application calculations, as well as future capacity calculations, for that applicant. The applicant must document where the potential patients for this new service will come from and where they are currently being served, to include the expected shift in patient volume from existing providers.
7. Expansion of an existing service, whether the expansion occurs at the existing site or at an alternate location in the service area, shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the past two years and can project a minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation. If the additional equipment is a specialized radiotherapy unit as described in either Standards 2, 3 or 4 above, then the existing provider may propose an annual capacity for that additional equipment, based on the specialized use of the equipment by that applicant. If the applicant can justify this proposed annual capacity, then this capacity will be used in CON application calculations, as well as future capacity calculations,

for that applicant.

8. The applicant shall project the utilization of the service and document referral sources for patients within its service area, including letters of support from physicians and health care facilities indicating a willingness to refer patients to the proposed service.
9. The applicant must affirm the following:
 - a. All treatments provided will be under the control of a board certified or board eligible radiation oncologist;
 - b. The applicant will have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent;
 - c. The applicant will have access to simulation equipment capable of precisely producing the geometric relationships of the equipment to be used for treatment of the patient;
 - d. The applicant will have access to a custom block design and cutting system; and
 - e. The institution shall operate its own tumor registry or actively participate in a central tumor registry.

The [Megavoltage Visits Chart](#) and [Radiotherapy Chart](#) are located in Chapter XIII of this Plan at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for these services:

1. Compliance with the Need Outlined in this Section of the Plan;
2. Community Need Documentation;
3. Distribution (Accessibility);
4. ~~Projected Revenues;~~
5. ~~Projected Expenses; Medically Underserved Groups; and~~
- 6.4. ~~Financial Feasibility; and~~
- 7.5. ~~Cost Containment.~~

~~Radiotherapy services are distributed statewide and are located within sixty (60) minutes' travel time for the majority of residents of the State.~~ The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of

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Need applications for this service.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS FOR STEREOTACTIC RADIOSURGERY

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1. The capacity of a dedicated Stereotactic Radiosurgery unit is 300 procedures annually. This is based on an average of two procedures per day times three days per week times 50 weeks per year.

~~2. The service area for a dedicated Stereotactic Radiosurgery unit is defined as all facilities within 90 minutes one-way automobile travel time.~~

~~2.~~

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3. New Radiosurgery services shall only be approved if the following conditions are met:

- a. All existing dedicated Stereotactic Radiosurgery units in the service area have performed at a combined use rate of 80 percent of capacity for the most recent year; and
- b. An applicant must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of service, without reducing the utilization of existing units below the 80 percent threshold.

4. Expansion of an existing radiosurgery service shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the prior two years and can project a minimum of 200 procedures per year on the additional equipment within three years of its implementation.

5. The applicant shall project the utilization of the service, to include:

- a. Epidemiological evidence of the incidence and prevalence of conditions for which radiosurgery treatment is appropriate, to include the number of potential patients for these procedures;
- b. The number of patients of the applicant who were referred to other radiosurgery providers in the preceding three years and the number of those patients who could have been served by the proposed service; and
- c. Current and projected patient origin information and referral patterns for the facility's existing radiation therapy services. The applicant shall document the number of additional patients, if any, that will be generated through changes in referral patterns, recruitment of specific physicians or other changes in circumstances.

6. The applicant must include letters of support from physicians and health care

facilities indicating a willingness to refer patients to the proposed service.

7. The applicant must document that protocols will be established to assure that all clinical radiosurgery procedures performed are medically necessary and that alternative treatment modalities have been considered.
8. The applicant must affirm the following:
 - a. The radiosurgery unit will have a board certified neurosurgeon and a board certified radiation oncologist, both of whom are trained in stereotactic radiosurgery;
 - b. The applicant will have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent;
 - c. Dosimetry and calibration equipment and a computer with the appropriate software for performing radiosurgical procedures will be available;
 - d. The applicant has access to a full range of diagnostic technology, including CT, MRI and angiography; and
 - e. The institution shall operate its own tumor registry or actively participate in a central tumor registry.
9. Due to the unique nature and limited need for this type of equipment, the applicant should document how it intends to provide accessibility for graduate medical education students in such fields as neurosurgery and oncology.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for these services:

- ~~1. Compliance with the Need Outlined in this Section of the Plan;~~
- ~~2.1. Community Need Documentation;~~
- ~~3.2. Distribution (Accessibility);~~
- ~~4. Projected Revenues;~~
- ~~5.3. Projected Expenses; Medically Underserved Groups;~~
- ~~6.4. Financial Feasibility Record of the Applicant; and~~
- ~~7.5. Cost Containment.~~

The service area for a dedicated Stereotactic Radiosurgery unit is defined as all facilities within ninety (90) minutes' travel time. The benefits of improved accessibility will be equally

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weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

CHAPTER X

POSITRON EMISSION TECHNOLOGY

POSITRON EMISSION TOMOGRAPHY (PET) AND PET/CT

Positron Emission Tomography (PET) uses small concentrations of radioactive material injected into the blood to capture color images of cellular metabolism. The tracer nucleotide most frequently used is FDG (Fluorodeoxyglucose). PET allows the study of metabolic processes such as oxygen consumption and utilization of glucose and fatty acids. Cancer cells utilize more glucose than normal cells, so PET can be used to reveal the presence or track the spread of cancer. It is quantitative and very sensitive, so only small amounts of isotopes are needed.

PET was developed in the 1970s and was primarily used for research focusing on cerebral function and detection and assessment of coronary artery disease. Recent research has centered on the diagnosis and staging of cancer and neurological applications such as epilepsy, Alzheimer's and Parkinson's diseases. PET is covered for Medicare patients with lung, breast, colorectal, head, neck and esophageal cancers; melanomas; certain thyroid diseases; neurology; and heart disease uses.

The process takes approximately 45 minutes to an hour to perform. A Computerized Tomography (CT) scanner produces cross-sectional images of anatomical details of the body. These images are taken separately, and fused with the PET images for interpretation. Several manufacturers have now developed combined PET/CT scanners that can acquire both image sets simultaneously, giving radiologists a more complete picture in about half the time.

It is anticipated that PET and PET/CT will become a standard diagnostic modality in the fields of cardiology, oncology and neurology. This technology is often available in health care facilities providing specialized therapeutic services such as open heart surgery and radiation oncology. The addition of a CT component to an existing PET service is not considered to be a new service that would trigger Certificate of Need review and is interpreted by the Department to be the replacement of like equipment with similar capabilities.

CERTIFICATE OF NEED STANDARDS*

* In the standards below, PET and PET/CT are used interchangeably.

1. Hospitals that provide specialized therapeutic services (open heart surgery and/or radiation therapy) should have either fixed or mobile PET services for the diagnosis of both inpatients and outpatients. Other hospitals must document that they provide a sufficient range of comprehensive medical services that would justify the need for

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~~PET services. Applicants for a freestanding PET service not operated by a hospital must document referral agreements from health care providers that would justify the establishment of such services.~~

- ~~2. Full-time PET scanner service is defined as having PET scanner services available five days per week. Fixed PET scanners are considered to be in operation five days per week. Capacity is considered to be 1,500 procedures annually. For PET/CT equipment, only procedures that utilize the PET component should be counted; procedures using the CT component as a stand-alone scanner are not included. Capacity for shared mobile services will be calculated based on the number of days of operation per week at each participating facility.~~
- ~~3. Applicants proposing new fixed PET services must project at a minimum 750 PET clinical procedures per year (three clinical procedures/day x 250 working days) by the end of the third full year of service. The projection of need must include proposed utilization by both patient category and number of patients to be examined, and must consider demographic patterns, patient origin, market share information, and physician/patient referrals. An existing PET service provider must be performing at least 1,250 clinical procedures (five clinical procedures x 250 days) per PET unit annually prior to the approval of an additional PET machine.~~
- ~~4. In order to promote cost-effectiveness, the use of shared mobile PET units should be considered. Applicants for a shared mobile scanner must project an annual minimum of three clinical procedures/day times the number of days/week the scanner is operational at the facility by the end of the third full year of service.~~
- ~~5. The applicant must demonstrate through cooperative and sharing agreements and letters of support how it will accommodate physicians, other health care institutions and patients from its own region and beyond.~~
- ~~6. The applicant agrees in writing to provide to the Department utilization data on the operation of the PET service.~~
- ~~7. The Department encourages all applicants and providers to share their outcome data with appropriate registries and research studies designed to improve the quality of patient care.~~
- ~~8. CMS requires that a provider seeking Medicare reimbursement must be accredited after January 1, 2012.~~

~~The Positron Emission Tomography (PET) and PET-CT Utilization Chart is located in Chapter XIII of this Plan.~~

POSITRON EMISSION MAMMOGRAPHY (PEM)

Positron Emission Mammography (PEM) is a form of PET that uses high-resolution detection technology for imaging the breast. It creates images that are more easily compared to mammography since they are acquired in the same position. As with PET, a radiotracer is administered and the camera is used to provide a higher resolution image. However, the administered dose of tracer is only about half the amount of whole-body PET, which reduces the radiation dose to the patient.

PEM imaging is used for pre-surgical planning and staging, monitoring response to therapy, and monitoring for recurrence of breast cancer. It detects lesions as small as 1.6 mm, which is not possible with whole-body PET. Three-dimensional reconstruction of the PEM images is also possible. PEM drastically reduces the number of false positives resulting in unnecessary biopsies incurred by patients using conventional mammography.

The actual scan takes 4-10 minutes and the entire process takes approximately 40 minutes to perform. The process requires a nuclear medical technologist certified to inject radiopharmaceuticals for handling of FDG, and either a mammography or nuclear medicine technologist to perform patient positioning and biopsy.

PEM was cleared for marketing by the U.S. Food and Drug Administration (FDA) in August of 2003.

CERTIFICATE OF NEED STANDARDS

1. PEM scanners are considered to be in operation five days per week, but because of their limited focus no capacity standard is established.
2. Hospitals that provide comprehensive cancer treatment services (including radiation therapy) are appropriate locations for fixed or mobile PEM services for the detection of breast cancer. Other hospitals must document that they treat a sufficient number of breast cancer patients that would justify the need for PEM services.
3. The applicant must demonstrate through cooperative and sharing agreements and letters of support how it will accommodate physicians, other health care institutions and patients from its own region and beyond.
4. The applicant agrees in writing to provide to the Department utilization data on the operation of the PEM service.
5. The Department encourages all applicants and providers to share their outcome data with appropriate registries and research studies designed to improve the quality of patient care.

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. — Compliance with the Need Outlined in this Section of the Plan;
2. — Community Need Documentation;
3. — Distribution (Accessibility);
4. — Acceptability;
5. — Financial Feasibility;
6. — Ability of the Applicant to Complete the Project; and
7. — Cost Containment.

The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

CHAPTER XI

OUTPATIENT FACILITIES

Outpatient facilities provide community service for the diagnosis and treatment of ambulatory patients that is operated in connection with a hospital or as a freestanding facility under the professional supervision of a licensed physician. These facilities serve patients who do not require hospitalization and makes available a range of diagnostic and treatment services. Hospital-based outpatient departments vary in scope, but generally include diagnostic laboratory, radiology, and clinical referral services.

AMBULATORY SURGICAL FACILITY

Ambulatory surgery, often described as outpatient or same-day surgery, may be provided in either a hospital or a freestanding Ambulatory Surgical Facility (ASF). An ASF is a distinct, freestanding, entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures, and/or services, for which patients are scheduled to arrive, receive surgery, or related care, treatment, procedures, and/or services, and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff (open medical staff). This definition does not apply to any facility used as an office or clinic for the private practice of licensed health care professionals.

For purposes of this Plan, an endoscope is defined as a flexible, semi-flexible or rigid instrument, which may or may not have a light attached, that is inserted into a natural orifice in a non-sterile, clean environment, to visually inspect for purposes of screening and diagnosis and to perform therapeutic treatment of the interior of a bodily canal or a hollow organ (such as the colon, bladder, stomach or nasal sinuses).

~~An Endoscopy ASF is defined as one organized, equipped, and operated exclusively for the purpose of performing surgical procedures or related treatments through the use of an endoscope. Any appropriately licensed and credentialed medical specialist can perform endoscopy only surgical procedures or related treatments at an Endoscopy ASF.~~

A substantial increase has occurred in both the number and percentage of ambulatory surgeries performed and in the number of approved ASFs. This trend has generally been encouraged because many surgical procedures can be safely performed on an outpatient basis at a lower cost.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The county in which the proposed facility is to be located is considered to be the

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service area for inventory purposes. The applicant may define a proposed service area that encompasses additional counties.

2. The applicant must identify the physicians who are affiliated or have an ownership interest in the proposed facility by medical specialty. These physicians must identify where they currently perform their surgeries and whether they anticipate making any changes in staff privileges or coverage should the application be approved.
3. For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. For the expansion of an existing facility, the applicant must provide patient origin information on the current facility.
4. The applicant must document the need for the expansion of or the addition of an ASF, based on the most current utilization data available. This need documentation must include the projected number of surgeries or endoscopic procedures to be performed by medical specialty. The existing resources must be considered and documentation presented as to why the existing resources are not adequate to meet the needs of the community.
5. It is recommended that an application for a new ASF should contain letters of support from physicians in the proposed service area other than those affiliated with the proposed facility.
6. The applicant must document the potential impact that the proposed new ASF or expansion of an existing ASF will have upon the existing service providers and referral patterns.
7. ~~All new Certificate of Need approvals by the Department will not restrict the specialties of ASFs. However, for an ASF approved to perform only endoscopic procedures, another Certificate of Need would be required before the center could provide other surgical specialties. The applicant must document whether it will restrict surgeries by specialty. Applicants who wish to restrict surgeries by specialty understand that another Certificate of Need would be required before the ASF could provide other surgical specialties. Applicants seeking to perform only endoscopic procedures are considered restricted.~~
8. Before an application for a new general Ambulatory Surgery Facility can be accepted for filing in a county having a current population of less than 100,000 people, all general ASFs in the county must have been licensed by the Department and operational for an entire year and must have submitted data on the Department's

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annual questionnaire to allow for a determination of their utilization. The requirements that all ASFs must have been licensed and operational for an entire year and submitted utilization data to the Department will not be applied to applicants for an ASF filing in a county having a current population of greater than 100,000 people.

9. Endoscopy suites are considered separately from other operating rooms and therefore are not considered competing applicants for Certificate of Need review purposes. Before an application for a new endoscopy-only ASF can be accepted for filing in a county having a current population of less than 100,000 people, all ASFs with endoscopy suites in the county must have been licensed by the Department and operational for an entire year and must have submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The requirements that all ASFs with endoscopy suites must have been licensed and operational for an entire year and submitted utilization data to the Department will not be applied to applicants for a new endoscopy-only ASF filing in a county having a current population of greater than 100,000 people.
10. The approval of a new general or endoscopy-only ASF in a county does not preclude an existing facility from applying to expand its number of operating rooms and/or endoscopy suites. The merger of two existing ASFs in a county to construct a consolidated ASF does not constitute a "new ASF" for the purpose of interpreting Standards 8 and 9.
11. The applicant for a new ambulatory surgery facility must provide a written commitment that the facility will accept Medicare and Medicaid patients, and that unreimbursed services for indigent and charity patients will be provided at a percentage that is comparable to all other existing ambulatory surgery facilities, if any, in the service area.

Facilities providing ambulatory surgery services must conform to local, state, and federal regulatory requirements and must commit to seek accreditation from CMS or any accrediting body with deemed status. Ambulatory surgical services are generally available within 30 ~~minutes~~minutes, one-way automobile travel time of most South Carolina residents. Most ASFs operate five days a week, with elective surgery being scheduled several days in advance.

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The [Ambulatory Surgical Facility Utilization Chart](#) is located in Chapter XIII of this Plan.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Compliance with the Need Outlined in this Section of the Plan;

2. Adverse Effects on Other Facilities
3. Community Need Documentation;
4. Distribution (Accessibility);
5. ~~Financial Feasibility~~ Record of the Applicant;
6. Cost Containment;
7. Projected Revenues;
8. Projected Expenses;
9. Ability of the Applicant to Complete the Project; and
10. Staff Resources.

The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

FREESTANDING EMERGENCY HOSPITAL SERVICES

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~~All hospital emergency departments are sub-categorized into four levels of service from I to IV, with I being the highest level of care. These categories are based on modified Joint Commission standards and adopted by the State EMS Advisory Council. Each facility must comply with the following paragraphs corresponding to their designated level of care. These standards do not constitute Certificate of Need criteria. All segments of the population should have basic emergency services available within 30 minutes one-way travel time.~~

~~Level I: Offers comprehensive emergency care 24 hours a day, with at least one physician experienced in emergency care on duty in the emergency care area. There is in-hospital physician coverage by members of the medical staff or by senior-level residents for at least medical, surgical, orthopedic, obstetric/gynecologic, pediatric, and anesthesia services. Other specialty consultation is available within approximately 30 minutes; initial consultation through two-way voice communication is acceptable.~~

~~Level II: Offers emergency care 24 hours a day, with at least one physician experienced in emergency care on duty in the emergency care area, and with specialty consultation available within approximately 30 minutes by members of the medical staff or by senior-level residents. The hospital's scope of services includes in-house capabilities for managing physical and related emotional problems, with provision for patient transfer to another organization when needed.~~

~~Level III: Offers emergency care 24 hours a day, with at least one physician available to the emergency care area within approximately 30 minutes through a medical staff call roster. Specialty consultation is available by request of the attending medical staff member or by transfer to a designated hospital where definitive care can be provided.~~

~~Level IV: Offers reasonable care in determining whether an emergency exists, renders lifesaving first aid, and makes appropriate referral to the nearest organization that is capable~~

~~of providing needed services. The mechanism for providing physician coverage at all times is defined by the medical staff. The popularity of freestanding emergency hospital services is increasing as a means of providing ready access to such services at the community level.~~

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CERTIFICATE OF NEED PROJECTIONS AND STANDARDS FOR FREESTANDING EMERGENCY SERVICES

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1. *A Certificate of Need is required to establish a freestanding emergency service (also referred to as an off-campus emergency service).*
2. All off-campus emergency services must be an extension of an existing hospital's emergency service in the same county, unless the applicant is proposing to establish a freestanding emergency service in a county that does not have a licensed hospital. The hospital must have a license that is in good standing and must be in operation to support the off-campus emergency services.
3. [Regulation 61-16](#) will be used to survey off-campus emergency services, specifically including 24 hour/7 day per week physician coverage on site.
4. An off-campus emergency service must have written agreements with Emergency Medical Services providers and surrounding hospitals regarding serious medical problems, which the off-campus emergency service cannot handle.
5. The physical structure must meet Section 12-6 of the Life Safety Code, *New Ambulatory Health Care Centers*, and must specifically have an approved sprinkler system.

6. ~~The applicant must demonstrate need for this service by documenting where the potential patients for this proposed service will come from and why they are not being adequately served by the existing services in the area. capacity constraints within existing emergency departments in the service area and/or a travel time of greater than 15 minutes to an existing emergency department in the service area.~~

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The [Freestanding Emergency Services Chart](#) is located ~~at the end of this Chapter, in Chapter XIII of this Plan.~~

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

- ~~1. Compliance with the Need Outlined in this Section of the Plan;~~
1. Community Need Documentation;
2. Distribution (Accessibility);

3. Medically Underserved Groups;
4. Resource Availability; and
5. Financial Feasibility Record of the Applicant.

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Access to emergency medical services should be available within fifteen (15) minutes travel time for the majority of residents of the State. The benefits of improved accessibility will be equally weighed without weigh the adverse effects of duplication in evaluating Certificate of Need applications for this service.

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TRAUMA-REFERRAL SYSTEM

~~The morbidity and mortality of a patient is negatively affected if trauma services are not provided in the first hour after an injury. This concept is often referred to as the "golden hour" to emphasize the need to provide timely care to trauma patients. The Department's Division of Emergency Medical Services (EMS) recognizes the National Fire Protection Association's benchmark for the organization and deployment for emergency medical operations to the public. The NFPA 1710 requires a turnout time of one (1) minute with a four (4) minute or less arrival of the first responder at an emergency medical incident on ninety percent (90%) of all calls.~~

~~EMS has developed and implemented a trauma-referral system throughout the state. This system allows any hospital desiring and qualifying as a trauma center to become so designated. The following is a brief description of the criteria for each of the three levels of Trauma Centers. Emergency Departments in all trauma centers are required to have adequate staff to include Emergency Department physicians in-house 24 hours per day.~~

~~Level I: A Level I facility is a regional trauma center that provides the highest level of trauma services available. It must possess an adequate depth of resources and personnel to meet this central role. The facility must have a surgically directed Intensive Care Unit (ICU) and in-house physician coverage at all times. The facility must possess an adequately staffed operating room that is immediately available to treat trauma victims. The operating room staff may not have duties requiring their presence outside of the operating room, and in-house anesthesia services must be available 24 hours a day. A mechanism must exist for staffing a second operating room if the first room is occupied. The facility must have a full spectrum of specialists available including cardiology, infectious disease, pulmonary medicine, and nephrology along with adequate support staff.~~

~~Level II: A Level II facility is a hospital that provides initial trauma services to all trauma victims. It must possess a surgical director or co-director for the ICU and have physician coverage in the emergency department whenever there is an emergency in the ICU. The facility must possess an adequately staffed operating room that is readily available to treat trauma victims. A mechanism must exist for staffing a second operating room if the first room is occupied. The facility must have surgical, internal medicine and pulmonary~~

specialists available at all times with the ability to order specialty consultations for internal medicine, cardiology, infectious disease, pulmonary medicine, and gastroenterology as needed.

Level III: A Level III facility provides prompt assessment, resuscitation, emergency operations and stabilization to trauma victims. It is led by a trauma surgeon who remains in charge of multiple-injured adult trauma patients in the ICU. When a patient is critically ill, there must be a mechanism to promptly provide ICU physician coverage 24 hours per day. The facility must have an ongoing performance improvement and patient safety (PIPS) program to review admissions and arrange transfers to ensure the appropriateness of medical care. The facility must possess an adequately staffed operating room that is readily available to treat trauma victims. Orthopedic surgery and internal medicine specialists must be available.

CHAPTER XII

LONG-TERM CARE FACILITIES AND SERVICES

NURSING FACILITIES

Nursing facilities provide inpatient care for convalescent or chronic disease residents who require nursing care and related medical services. This care is performed under the general direction of persons licensed to practice medicine or surgery in the State. Facilities furnishing primarily domiciliary care are not included. The licensing list of nursing facilities also denotes the facilities that have Alzheimer's units. For more specific detail about nursing facilities, refer to [Regulation 61-17](#) (*Standards for Licensing Nursing Homes*).

A ratio of 39 beds/1,000 population age 65 and over is used to project the need for ~~2015~~2017. Since the vast majority of patients utilizing nursing facilities are 65 years of age or older, only this segment of the population is used in the need calculations. A two-year projection is used because nursing facilities can be constructed and become operational in two years.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Bed need is calculated on a county basis. ~~Additional beds may be approved in counties with a positive bed need up to the need indicated using the ratio of 39 beds/1,000 population age 65 and over.~~

~~2.1.~~ When a county shows excess beds, additional beds will not be approved, except to allow an individual nursing facility to add some additional beds in order to make more economical nursing units. These additions are envisioned as small increments in order to increase the efficiency of the nursing home. This exception for additional beds will not be approved if it results in a three bed ward. A nursing facility may add up to 16 additional beds per nursing unit to create either 44 or 60 bed nursing units, regardless of the projected bed need for the county. The nursing facility must document how these additional beds will make a more economical unit(s).

~~3.2.~~ Some Institutional Nursing Facilities are dually licensed, with some beds restricted to residents of the retirement community and the remaining beds are available to the general public. The beds restricted to residents of the retirement community are not eligible to be certified for Medicare or Medicaid. Should such a facility have restricted beds that are inadvertently certified, the facility will be allowed to apply for a Certificate of Need to convert these beds to general nursing home beds, regardless of the projected bed need for that county.

The [Long-Term Care Bed Need Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered the most important in evaluating Certificate of Need applications for these beds or facilities:

1. ~~Compliance with the Need Outlined in this Section of the Plan~~Community Need Documentation;
2. Projected Revenues;
3. Projected Expenses;
4. Net Income;
5. Methods of Financing;
6. ~~Financial Feasibility~~Staff Resources;
7. Record of the Applicant; and
8. Distribution (accessibility).

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Because nursing facilities are located within approximately thirty (30) ~~minutes~~minutes' travel time for the majority of the residents of the State and at least one nursing facility is located in every county, no justification exists for approving additional nursing facilities or beds that are not indicated as needed in this Plan. The major accessibility problem is caused by the lack of Medicaid funding since the Medicaid Program pays for approximately 65% of all nursing facility residents. This Plan projects the need for nursing facility beds by county. The benefits of improved accessibility do not outweigh the adverse effects caused by the duplication of any existing beds or the placement of Medicaid funds for the beds.

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MEDICAID NURSING HOME PERMITS

The Medicaid Nursing Home Permit Act, formerly known as the Nursing Home Licensing Act of 1987, sets forth a regulatory scheme whereby Medicaid nursing home permits and Medicaid patient days are allocated in South Carolina. A long-term care facility (nursing home) must obtain a Medicaid Nursing Home Permit from the Department in order to serve Medicaid patients. A Medicaid patient is a person who is eligible for Medicaid (Title XIX) sponsored long-term care services. Each year, the South Carolina General Assembly establishes the maximum number of Medicaid patient days the Department is authorized to issue. A Medicaid patient day is a day of nursing home care for which the holder of a Medicaid nursing home Permit can receive Medicaid reimbursement. The South Carolina Department of Health and Human Services provides the Department with the total number of Medicaid patient days available so the Department may distribute those patient days amongst Permit holders.

The [Medicaid Patient Days and Medicaid Beds Requested & Authorized Chart](#) is located in ~~Chapter XIII of this Plan at the end of this Chapter.~~

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COMMUNITY LONG-TERM CARE (CLTC) PROGRAM

South Carolina is seeking to increase access to long-term care facilities through a number of different programs. The Community Long-Term Care Project (CLTC) provides mandatory pre-admission screening and case management to Medicaid-eligible individuals who are in need of applying for nursing facility placement under the Medicaid program. It also provides several community-based services for Medicaid participants who prefer to receive care in the community rather than institutional care. In certain counties, those services include:

Adult Day Healthcare: CLTC offers Adult Day Health Care to individuals enrolled in the Community Choices Waiver. This is medically supervised care and services provided at a licensed day care center. Transportation to and from the home is provided within 15 miles of the center.

Attendant/Personal Assistance: CLTC offers attendant services to individuals enrolled in the Community Choices Waiver. Nurses assist by observing care and helping consumers develop skills in managing their attendant. Services may include assistance with general household activities; help with activities such as bathing, dressing, preparing meals, and housekeeping; and observing health signs.

Care Management (Case Management - Service Coordination): CLTC assigns a nurse to help determine the services for which the participant qualifies and what services will best meet the needs of an individual enrolled in the Community Choices Waiver. Nursing Facility Transition Services may also be offered to help a participant residing in a nursing facility return to the community.

Companion (Sitter): CLTC provides an approved companion to provide supervision of an individual and short-term relief for regular caregivers to individuals enrolled in the Community Choices Waiver.

Home Repair/Modification Assistance: CLTC helps provide pest control services, ramps, heater fans and air conditioners to individuals enrolled in the Community Choices Waiver. It can also help make minor adaptations to non-rental property for the safety and health of the Medicaid participant.

Medical Equipment/Personal Care Supplies: CLTC provides limited durable medical equipment and incontinence supplies (diapers, underpads, wipes, etc.) to individuals enrolled in the Community Choices Waiver.

Nutritional Supplement Assistance: CLTC's Community Choices Program provides 2 cases per month of Nutritional Supplements to its participants.

The Program for All-Inclusive Care for the Elderly (PACE) is a Medicaid State option that provides comprehensive long-term care to primarily elderly residents of the State. PACE is available to Medicaid participants who are certified as "nursing home" eligible, but prefer care from community services. Palmetto SeniorCare and The Methodist Oaks currently operate PACE programs in the State.

SPECIAL NEEDS FACILITIES

The South Carolina Department of Disabilities and Special Needs (DDSN) provides 24-hour care to individuals with complex, severe disabilities through five (5) in-state regional facilities located in Columbia, Florence, Clinton, Summerville and Hartsville. These facilities serve those individuals who cannot be adequately cared for by one of DDSN's community living options and focus on those with special needs, head and spinal cord injuries and pervasive development disorders. In 2014, the Centers for Medicare and Medicaid Services (CMS) issued its final rule on Home and Community Based Services (HCBS) that will, inter alia, ensure that individuals who receive services through Medicaid's HCBS programs have access to the benefits of community living. DDSN believes the HCBS initiative will affect its Day Programs and where its clients live. The South Carolina Department of Health and Human Services (DHHS) will be the lead agency in implementing HCBS which will be phased in over the next five (5) years.

INSTITUTIONAL NURSING FACILITY (RETIREMENT COMMUNITY NURSING FACILITY)

An institutional nursing facility means a nursing facility (established within the jurisdiction of a larger non-medical institution) that maintains and operates organized facilities and services to accommodate only students, residents or inmates of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

To be considered under this special bed category, the following criteria must be met:

1. The nursing facility must be a part of and located on the campus of the retirement community.
2. It must restrict admissions to campus residents.

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3. The facility may not participate in the Medicaid program.

There is no projection of need for this bed category. The applicant must demonstrate that the proposed number of beds is justified and that the facility meets the above qualifications. If approved by the Department, such a facility would be licensed as an "Institutional Nursing Home," and the beds generated by such a project will be placed in the statewide inventory in Chapter III. These beds are not counted against the projected need of the county where the facility is located. For established retirement communities, a generally accepted ratio of nursing facility beds to retirement beds is 1:4.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria, as outlined in Chapter 8 of [Regulation 61-15](#), are considered the most important in evaluating Certificate of Need applications for these beds or facilities:

1. Need for the Proposed Project;
2. Economic Consideration; and
3. Health System Resources.

Because Institutional Nursing Facility Beds are used solely by the residents of the retirement community, there is no justification for approving this type of nursing facility unless the need can be documented by the retirement center. The benefits of improved accessibility do not outweigh the adverse effects caused by the duplication of any existing beds or facilities.

SWING-BEDS

A Certificate of Need is not required to participate in the Swing Bed Program in South Carolina; however, the hospital must obtain Medicare certification.

[The Social Security Act \(Section 1883\(a\)\(1\), \[42 U.S.C. 1395tt\]\)](#) permits certain small, rural hospitals to enter into a swing bed agreement, under which the hospital can use its beds to provide either acute or SNF care, as needed. The hospital must be located in a rural area and have fewer than 100 beds.

Medicare Part A covers the services furnished in a swing bed hospital under the SNF PPS. The PPS classifies residents into one of 44 categories for payment purposes. To qualify for SNF-level services, a beneficiary is required to receive acute care as a hospital inpatient for a stay of at least three consecutive days, although it does not have to be from the same hospital as the swing bed. Typical medical criteria include daily physical, occupational and/or speech therapy, IV or nutritional therapy, complex wound treatment, pain management, and end-of-life care.

The [Swing-Bed Participants Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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HOSPICE FACILITIES AND HOSPICE PROGRAMS

Hospice is a centrally administered, interdisciplinary health care program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including, but not limited to home, outpatient and inpatient services provided directly or through written agreement. Inpatient services include, but are not limited to, services provided by a hospice in a licensed hospice facility.

A [Hospice Facility](#) means an institution, place or building licensed by the Department to provide room, board and appropriate hospice care on a 24-hour basis to individuals requiring such services pursuant to the orders of a physician.

The [Inpatient Hospice Facilities Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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A [Hospice Program](#) means an entity licensed by the Department that provides appropriate hospice care to individuals as described in the first paragraph above, exclusive of the services provided by a hospice facility.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

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1. *A Certificate of Need is only required for an Inpatient Hospice Facility; it is not required for the establishment of a Hospice Program.*
2. An Inpatient Hospice Facility must be owned or operated either directly or through contractual agreement with a licensed hospice program.
3. The applicant must document the need for the facility and justify the number of inpatient beds that are being requested.
4. The proposed facility must consider the impact on other existing inpatient hospice facilities.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. ~~Compliance with the Need Outlined in this Section of the Plan~~Community Need Documentation;
2. Distribution (Accessibility);
3. Community Need Documentation;
4. Acceptability;
5. ~~Financial feasibility~~Record of the Applicant; and
6. Staff Resources.

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Hospice services should be available within sixty (60) minutes' travel time for the majority of residents of the State. The benefits of improved accessibility will be weighed equally with the adverse effects of duplication in evaluating Certificate of Need applications for this facility type.

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HOME HEALTH

Home Health Agencies

Home Health Agency means a public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services. Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for (f) below, in a place of temporary or permanent residence used as the individual's home as follows:

Part-time or intermittent skilled nursing care as ordered by a physician or podiatrist and provided by or under the supervision of a registered nurse and at least one other therapeutic service listed below: (a) physical, occupational, or speech therapy; (b) medical social services; (c) home health aide services; (d) other therapeutic services; (e) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment and (f) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

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1. An applicant must propose home health services to cover the geographic area of an entire county and agree to serve residents throughout the entire county.

2. A separate application is required for each county in which services are to be provided.
3. A new home health agency may be approved if an applicant can demonstrate it will serve 50 or more patients projected to be in need in non-rural counties, or 25 or more patients projected to be in need in rural counties, through evidence that may include, but would not be limited to, the following:
 - a. Letters of support that identify need for additional home health services from physicians and other referral sources.
 - b. Evidence of underutilization of home health services.
 - c. Evidence of limited scope home health agency service including skilled nursing, physical therapy, occupational therapy, speech therapy, home health aides, and medical social workers.
 - d. Evidence of the denial or delay in the provision of home health services, including but not limited to long waiting lists or delays which exceed industry standards.
 - e. Evidence that one or more existing home health agencies has failed to meet the minimum patient service requirements set forth in paragraph 8 of this section of the Plan within two years of the initiation of patient services after receiving a home health license.
4. For the purposes of this Section, a rural county shall mean a county with a population of less than 50,000, according to the most recent projections of the South Carolina Revenue and Fiscal Affairs office as of the time the current Plan was adopted.
5. All home health agency services (Skilled Nursing, Physical Therapy, Occupational Therapy, Speech Therapy, Home Health Aide, and Medical Social Worker) should be available within a county. If there is no hospital in a county and the existing licensed home health agencies between them do not provide all of the services identified above, this may be cited as potential justification for the approval of an additional agency that intends to offer these services.
6. Specialty home health providers are exempt from the need calculation applicable to full-service home health agencies, but are otherwise subject to Certificate of Need.
7. The applicant should have a track record that demonstrates a commitment to quality services. There should be no history of prosecution, consent order, abandonment of

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patients in other business operations, or loss of license. However, any consent orders or loss of licenses related to licenses that were obtained from the Department between July 1, 2013 and May 22, 2014 without a Certificate of Need shall not be grounds for denial of a Certificate of Need application pursuant to this Section. The applicant must provide a list of all licensed home health agencies it operates and the state(s) where it operates them.

8. The applicant must document that it can serve at least 25 patients annually in each rural county for which it is licensed and 50 patients annually in each non-rural county for which it is licensed within two years of initiation of services. The applicant must assure the Department that, should it fail to reach this threshold number two years after initiation of services in a county, it will voluntarily relinquish its license for that county.
9. Nothing in this Section is intended to restrict the ability of the Department to approve more than one new Home Health Agency in a county at any given time.

The [Home Health Agency Utilization Chart](#) is located ~~in Chapter XIII of this Plan~~ at the end of this Chapter.

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RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria, as outlined in Chapter 8 of [Regulation 61-15](#), are considered to be the most important in reviewing Certificate of Need applications for this service:

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1. Compliance with the Need Outlined in this Section of the Plan;
2. Acceptability;
3. Distribution (Accessibility);
4. Medically Underserved Groups;
5. Record of the Applicant; and
6. Financial Feasibility.

The benefits of improved accessibility outweigh the adverse effects caused by the duplication of any existing service.

Pediatric Home Health Agencies

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Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and appropriate intermittent home

health skilled nursing services to these patients. Any such approved agency will not be counted in the county inventories for need projection purposes.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

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1. A separate Certificate of Need application will be required for each county for an agency that proposes to provide this specialized service to pediatric patients in multiple counties.
2. The applicant must document that there is an unmet need for this service in the county of application, and the agency will limit such services to the pediatric population 18 years or younger.
3. The applicant must document the full range of services that they intend to provide to pediatric patients.

Continuing Care Retirement Community Home Health Agencies

A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services and *does not require Certificate of Need review provided:*

- a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;
- b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and
- c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.

Staff from other areas of the continuing care retirement community may deliver the home health services, but at no time may staffing levels in any area of the continuing care retirement community fall below minimum licensing standards or impair the services provided. If the continuing care retirement community includes charges for home health services in its base contract, it is prohibited from billing additional fees for those services. Continuing care retirement communities certified for Medicare or Medicaid, or both, must comply with government reimbursement requirements concerning charges for home health

services. The continuing care retirement community shall not bill in excess of its costs. These costs will be determined on non-facility-based Medicare and/or Medicaid standards.

CHAPTER XIII

INVENTORIES & DETERMINATIONS OF NEED

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GLOSSARY

TERM	DEFINITION	SOURCE
▲ Adaptive Radiation Therapy (ART)	Patient setup and/or radiation delivery is evaluated and modified periodically during the treatment course based on imaging and dose measurements made prior to or during treatment.	South Carolina Health Plan
▲ Affiliated Hospitals	Two or more health care facilities, whether inpatient or outpatient, owned, leased, sponsored, or who have a formal legal relationship with a central organization and whose relationship has been established for reasons other than for transferring beds, equipment or services.	South Carolina Health Plan
▲ Ambulatory Surgical Facility (ASF)	A distinct, freestanding, entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures, and/or services, for which patients are scheduled to arrive, receive surgery, or related care, treatment, procedures, and/or services, and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff (open medical staff). This definition does not apply to any facility used as an office or clinic for the private practice of licensed health care professionals.	South Carolina Health Plan
▲ Basic Perinatal Center with Well Newborn Nursery (Level I)	Level I hospitals provide services for normal uncomplicated pregnancies. A full list of the requirements for a Level I Basic Perinatal Center with Well Newborn Nursery can be found at Regulation 61-16, Section 1306.A. <i>Certificate of Need review is not required to establish a Level I program.</i>	South Carolina Health Plan
▲ Bed Capacity	Bed space designated exclusively for inpatient care, including space originally designed or remodeled for inpatient beds, even though temporarily not used for such purposes.	South Carolina Health Plan
▲ Cardiac Catheterization	An invasive procedure where a thin, flexible catheter is inserted into a blood vessel; the physician then	South Carolina

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Procedure manipulates the free end of the catheter into the chambers or vessels of the heart. All activities performed during one clinical session, including angiocardiology, coronary arteriography, pulmonary arteriography, coronary angioplasty and other diagnostic or therapeutic measures and physiologic studies shall be considered one procedure. Health Plan

▲ Complex Neonatal Intensive Care Unit (Level IV) In addition to the requirements of Regulation 61-16, Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. A full list of the requirements for a Complex Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.E. A Level IV hospital need not act as a Regional Perinatal Center (RPC). *Certificate of Need Review is required to establish a Level IV program.* South Carolina Health Plan

▲ Comprehensive Catheterization Laboratory A dedicated room or suite of rooms in which PCI as well as diagnostic and therapeutic catheterizations are performed. They are located only in hospitals approved to provide open heart surgery, although diagnostic laboratories are allowed to perform emergent and/or elective therapeutic catheterizations in compliance with Standard 7 or 8 in the Plan. South Carolina Health Plan

▲ Comprehensive Rehabilitation Facility A facility operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program under competent professional supervision. It provides an intensive, coordinated team approach to care for patients with severe physical ailments and should be located where an extensive variety of professionals representing medical, psychological, social, and vocational rehabilitation evaluation and services are available. These beds are viewed as being comprehensive in nature and not limited only to a particular service or specialty. South Carolina Health Plan

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▲ Conformal Radiation Therapy (CRT) Since the target often has a complex shape, CT, MRI, or PET is used to create a 3-D image of the tumor. Using the image, the computer designs the radiation beams to be shaped exactly (conform) to the contour of the treatment area. South Carolina Health Plan

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▲ Continuing Care Retirement Community Home Health Agency A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services and *does not require Certificate of Need review provided:* South Carolina Health Plan

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- a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;
- b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and
- c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.

▲ Crisis Stabilization Bed (Local Inpatient Crisis Stabilization Bed) The South Carolina Department of Mental Health (DMH) has had substantial decreases in inpatient capacity, resulting in insufficient adult inpatient beds being available to meet the demand from referral sources for its beds. This has led to persons in a behavioral crisis waiting in hospital emergency rooms for an appropriate inpatient psychiatric bed to become available. DMH has attempted to alleviate this problem by means of its "Crisis Stabilization Program." South Carolina Health Plan

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▲ Critical Access Hospital (CAH) Hospitals eligible for increased reimbursement without having to meet all criteria for full-service acute care hospitals. They are intended to provide essential health services to rural communities. In order to qualify as a CAH, a hospital must be located in a rural county and be located more than 35 miles from any South Carolina Health Plan

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other hospital or CAH (15 miles for areas with only secondary roads). It must be part of a rural health network with at least one full-service hospital. They can have a maximum of 25 licensed beds and the annual average length of stay must be less than 4 days. Emergency services must be available 24 hours a day.

▲ Diagnostic Catheterization A cardiac catheterization during which any or all of the following diagnostic procedures or measures are performed: Blood Pressure; Oxygen Content and Flow Measurements; Angiocardiology, Coronary Arteriography; and Pulmonary Arteriography. The following ICD-9-CM Procedure Codes refer to diagnostic catheterizations:

37.21 Right Heart Cardiac Catheterization
37.22 Left Heart Cardiac Catheterization
37.23 Combined Right and Left Heart Cardiac Catheterization

▲ Diagnostic Catheterization Laboratory A dedicated room in which only diagnostic catheterizations are performed. South Carolina Health Plan

▲ Elective PCI Scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure. South Carolina Health Plan

▲ Electronic Portal Imaging Devices (EPIDs) EPIDs have been developed because of the increased complexity of treatment planning and delivery techniques. The most common EPIDs are video-based systems wherein on-line digital port images are captured and analyzed before or during treatment. These systems are used for pre-treatment verification of Intensity Modulated Radiation Therapy fields and to reduce errors in patient positioning. South Carolina Health Plan

▲ Emergent or Primary PCI Means that a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. South Carolina Health Plan

▲ Endoscope A flexible, semi-flexible or rigid instrument, which may or may not have a light attached, that is inserted into a South Carolina

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natural orifice in a non-sterile, clean environment, to visually inspect for purposes of screening and diagnosis and to perform therapeutic treatment of the interior of a bodily canal or a hollow organ (such as the colon, bladder, stomach or nasal sinuses).

Health Plan

▲ Endoscopy ASF One organized, equipped, and operated exclusively for the purpose of performing surgical procedures or related treatments through the use of an endoscope. Any appropriately licensed and credentialed medical specialist can perform endoscopy only surgical procedures or related treatments at an Endoscopy ASF.

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▲ Exempt, Exemption The following are exempt from Certificate of Need review:

[S.C. Code
Ann. Section
44-7-170](#)

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(1) The acquisition by a person of medical equipment to be used solely for research, the offering of an institutional health service by a person solely for research, or the obligation of a capital expenditure by a person to be made solely for research if it does not:

(a) affect the charges imposed by the person for the provision of medical or other patient care services other than the services that are included in the research;

(b) change the bed capacity of a health care facility; or

(c) substantially change the medical or other patient care services provided by the person.

A written description of the proposed research project must be submitted to the department in order for the department to determine if these conditions are met. A Certificate of Need is required in order to continue use of the equipment or service after the equipment or service is no longer being used solely for research.

(2) The offices of a licensed private practitioner whether for individual or group practice except as

provided for in [Section 44-7-160\(1\) and \(6\)](#).

(3) The replacement of like equipment for which a Certificate of Need has been issued which does not constitute a material change in service or a new service.

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Fractionation The practice of providing only a small fraction of the entire prescribed dose of radiation in each treatment or session. Individual treatment plans are created to minimize the side effects for normal tissue. The typical fractionation schedule for adults is once per day, five days a week. Hyperfractionation (Superfractionation) refers to radiation given in smaller doses twice a day. In Hypofractionation, individual doses are given less often than daily, such as in two-five sessions.

South Carolina Health Plan

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Freestanding Medical Detoxification Facilities Short-term residential facility, separated from an inpatient treatment facility, providing for medically supervised withdrawal from psychoactive substance-induced intoxication, with the capacity to provide screening for medical complications of alcoholism and/or drug abuse, a structured program of counseling, if appropriate, and referral for further rehabilitation. *A Certificate of Need is required for a medical detoxification program.*

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General Hospital A facility with an organized medical staff to maintain and operate organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and care of such persons over a period exceeding 24 hours and provides medical and surgical care of acute illness, injury or infirmity and may provide obstetrical care, and in which all diagnoses, treatment or care are administered by or performed under the direction of persons currently licensed to practice medicine and surgery in the State of South Carolina.

[S.C. Code of Regulations 61-16, Section 101\(1\)\(A\)](#)

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Health Care Facility Acute care, hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities,

[S.C. Code Ann. Section 44-7-130\(10\)](#)

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residential treatment facilities for children and adolescents, intermediate care facilities for person with intellectual disability, narcotic treatment programs, and any other facility for which Certificate of Need review is required by federal law.

▲ Health Service Clinically related, diagnostic, treatment, or rehabilitative services and includes alcohol, drug abuse, and mental health services for which specific standards or criteria are prescribed in the South Carolina Health Plan.

[S.C. Code Ann. Section 44-7-130\(11\)](#)

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▲ Home Health Agency A public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.

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▲ Home Health Service Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for (f) below, in a place of temporary or permanent residence used as the individual's home as follows:

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Part-time or intermittent skilled nursing care as ordered by a physician or podiatrist and provided by or under the supervision of a registered nurse and at least one other therapeutic service listed below: (a) physical, occupational, or speech therapy; (b) medical social services; (c) home health aide services; (d) other therapeutic services; (e) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment; and (f) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the

individual in connection with any such items or services is not included.

▲ **Hospice** A centrally administered, interdisciplinary health care program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including, but not limited to home, outpatient and inpatient services provided directly or through written agreement. *Home-based and outpatient hospice programs do not require Certificate of Need review.*

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▲ **Hospice Facility** An institution, place or building licensed by the Department to provide room, board and appropriate hospice care on a 24-hour basis to individuals requiring such services pursuant to the orders of a physician. *A Certificate of Need is required for a hospice facility.*

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▲ **Hospice Program** An entity licensed by the Department that provides appropriate hospice care to individuals as described in the first paragraph above, exclusive of the services provided by a hospice facility. *A Certificate of Need is not required for a hospice program.*

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▲ **Hospital** A facility organized and administered to provide overnight medical, surgical, or nursing care of illness, injury, or infirmity and may provide obstetrical care, and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

[S.C. Code
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Hospital may include residential treatment facilities for children and adolescents in need of mental health treatment which are physically a part of a licensed psychiatric hospital. This definition does not include facilities which are licensed by the Department of Social Services.

▲ **Hospital Bed** A bed for an adult or child patient. Bassinets for the newborn in a maternity unit nursery, beds in labor rooms, recovery rooms, and other beds used

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exclusively for emergency purposes are not included in this definition.

▲ **Image-Guided Radiation Therapy (IGRT)** Combines with IMRT or CRT to visualize the patient's anatomy during treatments. This allows for confirmation of beam location and adjustment of the beams if needed during treatments due to breathing. IGRT facilitates more accurate patient positioning and reduces healthy tissue damage.

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▲ **Inpatient Psychiatric Services** Those services provided to patients who are admitted to institutions for the evaluation, diagnosis, and treatment of mental, emotional, or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.

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▲ **Inpatient Treatment Facility** Short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital. *A Certificate of Need is required for an Inpatient Treatment Facility.*

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▲ **Institutional Nursing Facility** A nursing facility established within the jurisdiction of a larger non-medical institution that maintains and operates organized facilities and services to accommodate only students, residents or inmates of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project. To be considered under this special bed category, the following criteria must be met:

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1. The nursing facility must be a part of and

located on the campus of the retirement community.

2. It must restrict admissions to campus residents.
3. The facility may not participate in the Medicaid program.

There is no projection of need for this bed category. The applicant must demonstrate that the proposed number of beds is justified and that the facility meets the above qualifications.

▲ Intensity Modulated Radiation Therapy (IMRT)

Creates a 3-D radiation dose map to treat the tumor. It uses a multi-leaf collimator to modulate or control the outlines and intensity of the radiation field during cancer treatment. Due to its precision it can spare more healthy tissue, but it also requires detailed data collection and takes longer than conventional therapy.

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▲ Long-Term Acute Care Hospital (LTACH)

Hospitals with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients. They provide treatment to patients with complex medical conditions, such as strokes, cardiac care, ventilator dependency, wound care and post-surgical care.

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▲ Narcotic Treatment Program

Provide medications for the rehabilitation of persons dependent on opium, morphine, heroin or any derivative or synthetic drug of that group. Opioid maintenance therapy (OMT) is an umbrella term that encompasses a variety of pharmacologic and nonpharmacologic treatment modalities, including the therapeutic use of specialized opioid compounds such as methadone, suboxone and buprenorphine to psychopharmacologically occupy opiate receptors in the brain, extinguish drug craving and thus establish a maintenance state. *A Certificate of Need is required for a Narcotic Treatment Program.*

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▲ Nursing Facility

Facilities which provide inpatient care for convalescent or chronic disease residents who require nursing care and related medical services. Such nursing care and

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medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State. Facilities furnishing primarily domiciliary care are not included.

▲ Open Heart Surgery

An operation performed on the heart or intrathoracic great vessels. The thoracic cavity is typically opened to expose the heart, which is stopped and the blood is recirculated and oxygenated during surgery by a heart-lung machine.

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▲ Open Heart Surgical Procedure

An operation performed on the heart or intrathoracic great vessels within an open heart surgical unit. All activities performed during one clinical session shall be considered one procedure.

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▲ Open Heart Surgical Program

The combination of staff, equipment, physical space and support services which is used to perform open heart surgery. Adult open heart surgical programs should have the capacity to perform a full range of procedures, including:

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1. repair/replacement of heart valves;
2. repair of congenital defects;
3. cardiac revascularization;
4. repair/reconstruction of intrathoracic vessels;
and
5. treatment of cardiac traumas.

In addition, open heart programs must have the ability to implement and apply circulatory assist devices such as intra-aortic balloon and prolonged cardiopulmonary partial bypass.

▲ Open Heart Surgery Unit

An operating room or suite of rooms equipped and staffed to perform open heart surgery procedures; such designation does not preclude its use for other related surgeries, such as vascular surgical procedures. A hospital with an open heart surgery program may have one or more open heart surgery units.

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▲ Outpatient Facility

Provide treatment/care/services to individuals

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dependent upon or addicted to psychoactive substances and their families based on an individual treatment plan in a nonresidential setting. *A Certificate of Need is not required for outpatient facilities.*

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▲ Pediatric Home
Health Agency

Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the home health criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to these patients. Any such agencies are not counted in the county inventories for need projection purposes.

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▲ Pediatric Long-
Term Care Hospital
(PLATCH)

Specialized Healthcare Facilities that provide care for children up to age 21 who have complex medical conditions that require extensive care on a long-term basis. Care may be rehabilitative or palliative. Children must have ongoing health conditions that require both medical and nursing supervision and specialized equipment or services. Many patients are non-ambulatory and dependent on medical technology such as ventilators, feeding tubes, IV infusions, and mobility devices.

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▲ Percutaneous
Coronary
Intervention (PCI)

A therapeutic procedure to relieve coronary narrowing, such as Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Stent Implantation. These procedures may be performed on an emergent or elective basis. "Emergent or Primary" means that a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. An "Elective" PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure. therapeutic catheterization procedure used to revascularize occluded or partially occluded coronary arteries. A catheter with a balloon or a stent is inserted into the

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blood vessel and guided to the site of the constriction in the vessel. These procedures may be performed on an emergent or elective basis.

Person

An individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, a health care facility, a state, a political subdivision, or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.

[S.C. Code
Ann. Section
44-7-130\(15\)](#)

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Positron Emission
Mammography
(PEM)

A form of PET that uses high-resolution detection technology for imaging the breast. It creates images that are more easily compared to mammography since they are acquired in the same position. As with PET, a radiotracer is administered and the camera is used to provide a higher resolution image. However, the administered dose of FDG is only about half the amount of whole-body PET. PEM imaging is used for pre-surgical planning and staging, monitoring response to therapy, and monitoring for recurrence of breast cancer. Three-dimensional reconstruction of the PEM images is also possible.

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Positron Emission
Tomography (PET)

Uses small concentrations of radioactive material injected into the blood to capture color images of cellular metabolism. PET allows the study of metabolic processes such as oxygen consumption and utilization of glucose and fatty acids. Cancer cells utilize more glucose than normal cells, so PET can be used to reveal the presence or track the spread of cancer. It is quantitative and very sensitive, so only small amounts of isotopes are needed. PETs are now being combined with a Computerized Tomography (CT) scanner to create PET/CT scanners. In the Certificate of Need standards cited below, the terms PET and PET/CT are used interchangeably; the Department does not differentiate between these modalities. The addition of a CT component to an existing PET service is not considered to be a new service that would trigger Certificate of Need review and is interpreted by the

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Department to be the replacement of like equipment with similar capabilities.

▲ Regional Perinatal Center with Neonatal Intensive Care Unit (RPC)

In addition to the requirements of Regulation 61-16, Sections 1306.A through 1306.C, RPCs provide consultative, outreach, and support services to other hospitals in the region. A full list of the requirements for a Regional Perinatal Center can be found at Regulation 61-16, Section 1306.D. No more than one Regional Perinatal Center will be approved in each perinatal region. *The establishment of a Regional Perinatal Center requires Certificate of Need review.*

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▲ Residential Treatment Facility for Children and Adolescents

Operated for the assessment, diagnosis, treatment, and care of children and adolescents in need of mental health treatment. This means a child or adolescent up to age 21 who manifests a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree that child's capacity either to develop or to exercise age-appropriate or age-adequate behavior. The behavior includes, but is not limited to, marked disorders of mood or thought processes, severe difficulties with self-control and judgment, including behavior dangerous to self or others, and serious disturbances in the ability to care for and relate to others. These facilities provide medium to long-term care (6 months or longer). Treatment modalities are both medical and behavioral in nature.

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▲ Residential Treatment Program Facility

24-hour facilities offering an organized service in a residential setting, which is designed to improve the client's ability to structure and organize the tasks of daily living and recovery through planned clinical activities, counseling, and clinical monitoring in order to promote successful involvement or re-involvement in regular, productive, daily activity, and, as indicated, successful reintegration into family living. *A Certificate of Need is not required for a Residential Treatment Program.*

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▲ Social
Detoxification
Facility

Facilities which provide supervised withdrawal from alcohol or other drugs in which neither the client's level of intoxication nor physical condition is severe enough to warrant direct medical supervision or the use of medications to assist in withdrawal, but which maintains medical backup and provides a structured program of counseling, if appropriate, educational services, and referral for further rehabilitation. A *Certificate of Need* is not required for these facilities.

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▲ Specialty Perinatal
Center with Special
Care Nursery (Level
II)

In addition to the requirements of Regulation 61-16, Section 1306.A, Level II hospitals provide services for both normal and selected high-risk obstetrical and neonatal patients. A full list of the requirements for a Level II Specialty Perinatal Center can be found at Regulation 61-16, Section 1306.B. *Certificate of Need* review is not required to establish a Level II program.

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▲ Stereotactic Body
Radiation Therapy
(SBRT)

A precision radiation therapy delivery concept derived from cranial stereotactic radiosurgery. It is characterized by one to five fraction delivery of focal high-dose radiation while limiting dose to surrounding normal tissues. SBRT has become an established treatment technique for lung, liver, and spinal lesions.

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▲ Stereotactic
Radiation Therapy
(SRT)

An approach similar to Stereotactic Radiosurgery that delivers radiation to the target tissue. However, the total dose of radiation is divided into several smaller doses given over several days, rather than a single large dose. The treatment time per session typically ranges from 30 to 90 minutes for two-five sessions. It can be used to treat both brain and extracranial tumors.

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▲ Stereotactic
Radiosurgery (SRS)

A single-session procedure used to treat brain tumors and other brain disorders that cannot be treated by regular surgery. The radiation dose given in one session is usually less than the total dose that would be given with radiation therapy. However, the tumor receives a very high one-time dose of radiation with radiosurgery versus smaller fractions over time with

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radiation therapy. It is also known as Stereotaxic Radiosurgery or Radiation Surgery.

▲ Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III)	In addition to the requirements of Regulation 61-16, Sections 1306.A and 1306.B, Level III hospitals provide all aspects of perinatal care, including intensive care and a range of continuously available, sub-specialty consultation as recommended in the most recent edition of the <i>Guidelines for Perinatal Care</i> (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. A full list of the requirements for a Level III Subspecialty Perinatal Center with Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.C. <i>Certificate of Need Review is required to establish a Level III program.</i>	South Carolina Health Plan
▲ Swing-Bed	The Social Security Act (Section 1883(a)(1), [42 U.S.C. 1395tt]) permits certain small, rural hospitals to enter into a “Swing Bed” agreement, under which the hospital can use its beds to provide either acute or skilled nursing care, as needed. The hospital must be located in a rural area and have fewer than 100 beds. <i>A Certificate of Need is not required to participate in the Swing Bed Program.</i>	South Carolina Health Plan
▲ Therapeutic Catheterization	A cardiac catheterization during which any or all of the following interventional procedures are performed: PTCA; Thrombolytic Agent Infusion; Directional Coronary Atherectomy; Rotational Atherectomy; Extraction Atherectomy; Coronary Stent Implants and Cardiac Valvuloplasty. The following ICD-9-CM Procedure Codes refer to therapeutic catheterizations: 00.66 Percutaneous Transluminal Coronary Angioplasty (PTCA) 17.55 Transluminal Coronary Atherectomy 35.52 Repair of Atrial Septal Defect with Prosthesis, Closed Technique 35.55 Repair of Ventricular Septal Defect with Prosthesis, Closed Technique 35.96 Percutaneous Valvuloplasty 36.06 Insertion of Non-Drug Eluting Coronary Artery	South Carolina Health Plan

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Stent(s)

36.07 Insertion of Drug Eluting Coronary Artery
Stent(s)

36.09 Other Removal of Coronary Artery Obstruction

37.34 Excision or Destruction of Other Lesion or
Tissue of Heart, Endovascular Approach

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